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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

ROBERT BERG, Derivatively on Behalf of INTUITIVE SURGICAL, INC., Plaintiff, vs. GARY S. GUTHART, MARSHALL L. MOHR, LONNIE M. SMITH, DAVID J. ROSA, MARK J. MELTZER, JEROME J. MCNAMARA, AUGUSTO V. CASTELLO, SALVATORE J. BROGNA, COLIN MORALES, CRAIG H. BARRATT, ERIC H. HALVORSON, AMAL M. JOHNSON, ALAN J. LEVY, FLOYD D. LOOP, MARK J. RUBASH, GEORGE STALK JR., Defendants, – and – INTUITIVE SURGICAL, INC., Nominal Party.	Case No. VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTY, GROSS MISMANAGEMENT, ABUSE OF CONTROL AND UNJUST ENRICHMENT DEMAND FOR JURY TRIAL

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

1. Plaintiff Robert Berg ("Plaintiff"), by and through his undersigned attorneys, hereby submits this Verified Shareholder Derivative Complaint for Breach of Fiduciary Duty, Gross Mismanagement, Abuse of Control and Unjust Enrichment (the "Complaint") for the benefit of nominal defendant Intuitive Surgical, Inc. ("Intuitive" or the "Company") against certain members of its Board of Directors (the "Board") and executive officers seeking to remedy defendants' breaches of fiduciary duties and unjust enrichment from 2012 to the present (the "Relevant Period").

2. According to its public filings, Intuitive designs, manufactures, and markets da Vinci surgical systems ("da Vinci"), and related instruments and accessories. The Company's da Vinci surgical system reportedly translates a surgeon's natural hand movements, which are performed on instrument controls at a console, into corresponding micro-movements of instruments positioned inside the patient through small incisions or ports. The da Vinci surgical system reportedly consists of a surgeon's console, a patient-side cart, a 3-D vision system, a da Vinci skills simulator, and Firefly fluorescence imaging product that enable surgeons to perform various surgical procedures, including gynecologic, urologic, general surgery, cardiothoracic, and head and neck surgical procedures. The Company also manufactures EndoWrist instruments consisting of forceps, scissors, electrocautery, scalpels, and other surgical tools, which incorporate wrist joints for natural dexterity for various surgical procedures. In addition, the Company offers da Vinci single-site instruments and accessories that reportedly allow da Vinci Si surgical systems to work through a single incision; and EndoWrist One vessel sealer, a wristed single-use instrument intended for bipolar coagulation and mechanical transection of vessels up to 7 mm in anastomoses in general, gynecologic, and urologic surgery; and sells various accessory and tissue bundles that fit in the jaws of the instrument. Further, the Company provides the EndoWrist Stapler 45 instrument, a wristed

stapling instrument intended for resection, transaction, and/or creation of, such as sterile drapes, 3-D stereo endoscopes, camera heads, light guides, and other items that are used in conjunction with the da Vinci surgical system. Intuitive markets its products directly and through distributors in the United States and internationally.

NATURE OF THE ACTION

3. During the Relevant Period, defendants issued materially false and misleading statements regarding the Company's business and financial results. Specifically, defendants failed to disclose that the Company's flagship product, the da Vinci surgical system, was faulty, unsafe to use, and was causing injuries and death. During this time, Intuitive's stock traded as high as $588 per share on May 1, 2012.

4. As alleged herein, this shareholder derivative action concerns the harm caused to Intuitive from a series of materially false and misleading statements issued by Defendants concerning the Company's da Vinci surgical system, Intuitive's flagship product and source of revenues, and defendants' concerted efforts to conceal da Vinci's internally-known defects and the injuries it caused to patients, including death. Throughout the Relevant Period, Intuitive received thousands of injury and defect reports related to surgeries using da Vinci. The most dangerous injuries arose from burns to internal organs caused by the discharge of electricity (usually in the form of sparks), caused by the robot's instruments inside the patient. Despite the severity and multitude of reports, defendants systematically underreported these injuries and their seriousness to the United States Food and Drug Administration (the "FDA"). As the reports continued to increase, however, the FDA finally initiated an investigation in 2013, which culminated in the issuance of a warning letter on July 16, 2013 (the "FDA Warning Letter"). The FDA Warning Letter concluded that Intuitive had concealed information from the FDA, secretly recalled defective parts, and ignored known injuries to patients in its design process of critical da Vinci instruments.

5. The fact that Intuitive's revenues are dependent on the da Vinci system is evidenced by the simple fact that the da Vinci system and its accessory products are ***the Company's only product line***. Each da Vinci system principally consists of three or four robotic arms, depending on the model, which perform laparoscopic surgeries through tiny incisions. Sitting at a separate console away from the patient and looking into a viewfinder, the surgeon uses two joystick-like gadgets to control the robotic arms. Attached to the arms are various types of instruments, including forceps, scissors, and scalpels, as well as tiny cameras and lights. The instruments can be easily swapped through quick snap-and-release docks at the ends of the robotic arms. Defendants caused Intuitive to sell da Vinci systems to hospitals to perform numerous types of surgeries, including hysterectomies, prostatectomies, and cardiotomies.

6. Defendants had long been on notice that da Vinci was causing serious injuries to patients. After inspecting Intuitive's headquarters in April and May 2013, the FDA reported that defendants had received hundreds of complaints and reports between July 2009 and December 2011. The vast majority of these reports concerned a little rubber sleeve, inserted at the end of certain da Vinci metal instruments, designed as an insulating device to prevent electricity from radiating out. The plastic sleeves were referred to as tip covers (the "Tip Cover"). The critical defect consisted of cracks or slits that prevented the Tip Cover from properly insulating the metal instruments and allowed electricity or sparks to escape, an effect known as arcing. Because the arcing usually occurred outside of the surgeon's camera field of vision, blood vessels and organs were burned without the medical team's knowledge. Deaths occurred when patients hemorrhaged internally for days while the bleeding remained undetected after the surgery.

7. Defendants were on notice about the defective Tip Covers and quietly sought to take "corrective action" as early as October 2011. According to the FDA Warning Letter, "[t]his correction was in response to complaints and medical device reports (MDRs) for arcing through

damaged tip covers that caused patient injuries." But defendants did not report this corrective action to the FDA as required, which the FDA subsequently classified in the July 2013 FDA Warning Letter as a "Class II Recall." In addition to the Tip Cover correction, defendants initiated two other corrective actions in October 2011, both of which were concealed from the FDA.

8. Aware of the increase in injuries caused by the defective Tip Covers, and after having concealed the seriousness of the issue from the FDA by failing to report the October 2011 recall, defendants also engaged in a concerted effort to minimize the importance of the reports that did reach the FDA. As set forth in greater detail below, stringent FDA regulations require that hospitals report to the manufacturer (i.e. Intuitive) serious injuries arising from the use of da Vinci. In turn, these regulations also require Intuitive to submit these medical device reports, or MDRs, to the FDA. MDRs filed with the FDA are compiled in the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. To hide the da Vinci defects, however, defendants consistently underreported MDRs, misclassified them under the innocuous category of "other," even though scores qualified as "serious injury," and added self-serving disclaimers in the filed MDRs concerning the purported lack of evidence linking the injury or harm to a da Vinci defect.

9. In September 2012, the FDA met with defendants to address the Company's underreporting and misclassification of the MDRs. As a result, Intuitive was required to change its reporting policies by (i) reporting MDRs not previously submitted to the FDA, and (ii) upcoding many MDRs previously labeled "other" to "serious injury."

10. It was only after these significant changes to Intuitive's MDR reporting practices, and the material rise in serious MDR reports, that in January 2013 the FDA began a safety probe of the Company. The FDA probe suggests that, after the FDA realized in September 2012 that defendants had been improperly labeling the MDRs, the FDA did not fully trust the Company's role as a middleman between the hospital reports and those that Intuitive submitted to the agency. The

FDA thus sent out a survey directly to hospitals in January 2013 seeking, among other things, information concerning (i) problems or challenges with da Vinci, (ii) complications during surgeries, (iii) problem-causing da Vinci devices, and (iv) surgeons' familiarity with da Vinci recalls and corrective changes. In addition to this written survey, the safety probe also included one-hour interviews with surgeons.

11. *Bloomberg* news publicly disclosed the FDA probe on February 28, 2013, only five minutes before the stock market closed. The Company's stock price dropped $63 per share, from about $573 per share to $510 per share, resulting in the Company losing more than ten percent of its value.

12. Meanwhile, the defendants had been heavily selling their Company stock in unusual and suspicious trading. Between February 2012 and March 2013, certain of the defendants (including several members of the Board) sold 380,309 shares of their personally held Intuitive stock, reaping proceeds of over ***$207 million***.

13. Tellingly, most of these sales were made at a time when Intuitive stock had reached all-time highs exceeding $500 per share, and before the full truth about the true safety and risk profile of the Company emerged. The stock price had reached these historic highs because Intuitive had become a Wall Street darling propped-up by defendants' false and misleading statements and omissions. Defendants misleadingly emphasized the Company's 20%-plus growth in revenues and number of surgeries, while simultaneously touting da Vinci as "a new generation of surgery" that "combine[d] the benefits of minimally invasive surgery (MIS) for patients with the ease of use, precision, and dexterity of open surgery."

14. Defendants thus pounced on the perception of robotic surgery as the future, with minimal trauma, and the same (if not greater) benefits as open surgery. Defendants, however, did not disclose the known defects, patient injuries, and deaths, and their concerted efforts to conceal all

this from the FDA and the public.

15. Defendants' ability to conceal these defects and problems, however, was soon to end. After the FDA launched the safety probe in early 2013, it followed with a lengthy inspection of Intuitive's headquarters between April 1 and May 30, 2013. At the end of the inspection, the FDA issued a Form FDA-483 ("Form 483")[1] to defendant Guthart (defined further herein), a member of the Board, setting forth the objectionable conditions. There were four such observations, including the discovery by the FDA that Intuitive had carried out the secret recall of the Tip Covers in October 2011, as discussed above. In addition, and equally dangerous to patients' health, defendants were on notice since 2010 that surgeons needed to clean da Vinci instruments while inside the patient's bodies, and that to do so they scrubbed one instrument against another. This had consistently led to tears or holes in the Tip Covers that led to arcing that in turn caused injuries to patients. FDA regulations thus required defendants to address this "user need" through a rigorous and heavily regulated design control process. Defendants entirely ignored this user need, did not document it, and never even sought to address this health risk in flagrant violation of FDA regulations.

16. As news of the FDA safety probe, da Vinci's defects, and the risks posed to health began to spread, patients, surgeons, and hospitals started to cut back on da Vinci purchases and the number of procedures. For the first quarter of 2013, defendants caused Intuitive to thus report a rare slowdown in the rate of procedure growth. With only the month of March in the first quarter affected by the disclosure on February 28 of the FDA safety probe, first quarter revenues and sales

[1] An FDA Form 483 lists objectionable conditions observed by the FDA during a facility inspection. While the observations contained in a Form 483 report do not constitute a final agency determination regarding the facility's compliance with applicable laws and regulations, corrective action by the inspected company is expected. Indeed, an establishment may face legal sanctions available to the FDA, such as seizure, injunction, civil monetary penalties and prosecution, if it does not voluntarily correct serious conditions.

growth, nevertheless, were tempered.

17. The public disclosure of the FDA probe and the rise in MDRs that prompted it also led investigative journalists to examine da Vinci's safety record. Lengthy news articles revealing tragic injuries caused by da Vinci increasingly began to surface. On March 5, 2013, for example, *Bloomberg* published a story titled, "Robosurgery Suits Detail Injuries as Death Reports Rise." One such death was that of a 24 year-old woman who had suffered a lacerated artery while undergoing surgery for cervical cancer. The burned artery had not been discovered until eleven days later, which was too late. The autopsy concluded that the patient's death was a "therapeutic complication" resulting in hemorrhage and multi-organ failure.

18. Due to the onslaught of negative reports, in the second quarter ending June 30, 2013, the adverse impact on revenues and procedure growth was substantial. On July 8, 2013, defendants caused the Company to report preliminarily that second quarter 2013 revenues from da Vinci sales had declined six percent to $215 million, compared to $229 million in the second quarter of 2012. Intuitive also had sold only 143 systems, compared with 150 systems in the second quarter of 2012, and 164 systems in the first quarter of 2013. The Company thus had gone from rapid growth to a steep decline in only one quarter.

19. Wall Street analyst reports reflected surprise at the unexpected decline and its magnitude. JPMorgan Chase & Co.'s (" JP Morgan") report of July 8, 2013 called it "shocking": "The severity of the top line [revenue] shortfall, with the company posting revenues of $575M vs. consensus of $630 million [$622M JP Morgan] was shocking, and raises more questions than answers."

20. Ten days later, on July 18, 2013, defendants caused the Company to reveal that it had received the FDA Warning Letter dated July 16, 2013. A Warning Letter is the most serious agency communication and often the last step prior to seizure, injunction, and/or civil money

penalties. The FDA Warning Letter, in large part, formally determined that the observations listed in the Form 483 were violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and thus represented a significant escalation of the FDA's regulatory action.

21. According to the FDA Warning Letter, (i) the Tip Covers constituted "misbranded devices"; (ii) Intuitive knew that the Tip Covers in October 2011 posed a risk to health and, yet, Intuitive proceeded to conduct a secret recall while failing to report this "correction," thereby violating FDA reporting requirements; (iii) Intuitive also knew that the intraoperative cleaning of da Vinci instruments caused the Tip Covers to fail, leading to arcing, and yet ignored the problem, again violating FDA regulations including Current Good Manufacturing Practices; and (iv) after having been notified of these violations pursuant to the Form 483, Intuitive had submitted incomplete and inadequate responses to the FDA on June 7, 2013. Tellingly, the FDA Warning Letter added, "[t]he FDA has previously informed you of your firm's correction and removal violations in an untitled letter dated February 19, 2008, and FDA 483 Inspectional Observations issued on December 20, 2002." In saying this, the FDA was confirming that failing to report corrections and removals (*i.e.*, the secret recall) was an ongoing, unsolved issue with Intuitive.

22. The public disclosure of the FDA Warning Letter, after the market closed on July 18, 2013, marks the dramatic decline suffered in the price of the stock. The next day, Intuitive closed at $392 per share, falling under $400 per share for the first time in almost two years. Investors and the market understood that the risk posed by da Vinci, and the risk profile of Intuitive's stock, had materially and substantially increased, and that the Company's growth potential had materially and substantially decreased.

23. Indeed, the material negative change in the Company's risk profile and growth

outlook is best exemplified by the degree to which, under defendants' direction, Intuitive concealed the MDRs from the FDA.[2] Over one year since Intuitive began properly classifying and reporting MDRs after the September 2012 meeting with the FDA, the figures show that defendants had suppressed more than 40 percent of all MDRs. Indeed, for the prior twelve years, from 2000-2012, there were 5,333 da Vinci-related MDRs filed in total. This number grew dramatically to over 8,450 MDRs, after a staggering 3,117 da Vinci-related MDRs were filed with the FDA in the nine months from January 1 to September 30, 2013 alone.

24. After the above revelations seeped into the market, the Company's shares were fell dramatically. Further, as a result of defendants' breaches, the price of the Company's stock still has not recovered.

25. Accordingly, as a result of defendants' breaches, the Company has been damaged.

JURISDICTION AND VENUE

26. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(2) in that Plaintiff and defendants are citizens of different states and/or countries and the matter in controversy exceeds $75,000.00, exclusive of interests and costs. This Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. §1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

27. Venue is proper in this district because a substantial portion of the transactions and

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[2] There is currently a related securities class action against Intuitive and certain of the defendants named herein pending in the U.S. District Court for the Northern District of California, captioned *Spencer Abrams et al. v. Intuitive Surgical, Inc. et al.*, No. 5:13-cv-01920 (N.D.C.A.) (the "Securities Action"). On October 15, 2013, the lead plaintiff to the Securities Action filed a Consolidated Complaint for Violations of Federal Securities Laws (the "Securities Complaint"). While Plaintiff and his undersigned attorneys have conducted their own independent investigation of the wrongdoing alleged herein, many of the allegations herein are based upon allegations contained in the Securities Action.

wrongs complained of herein, including defendants' primary participation in the wrongful acts detailed herein, occurred in this district. One or more of the defendants either resides in or maintains executive offices in this district, and defendants have received substantial compensation in this district by engaging in numerous activities and conducting business here, which had an effect in this district.

INTRADISTRICT ASSIGNMENT

28. A substantial part of the events or omissions which give rise to the claims in this action occurred in the City of Sunnyvale, in the County of Santa Clara, and as such this action is properly assigned to the San Jose Division of this Court.

THE PARTIES

29. Plaintiff is a current shareholder of Intuitive and has been continuously since January 2009. Plaintiff is a citizen of Wisconsin. Plaintiff's verification is attached hereto.

30. Nominal party Intuitive is a Delaware corporation with its executive offices located at 1266 Kifer Road, Building 101, Sunnyvale, California 94086. According to its public filings, the Company designs, manufactures, and markets da Vinci surgical systems, and related instruments and accessories, EndoWrist instruments consisting of forceps, scissors, electrocautery, scalpels, and other surgical tools, and EndoWrist Stapler 45 instrument, a wristed stapling instrument intended for resection, transaction, and/or creation of, such as sterile drapes, 3-D stereo endoscopes, camera heads, light guides, and other items that are used in conjunction with the da Vinci surgical system.

31. Defendant Gary S. Guthart ("Guthart") has served as the Company's Chief Executive Officer ("CEO") since January 2010 and as the Company's President since 2007. Prior to that, Guthart served as the Company's Chief Operating Officer ("COO") since February 2006. In addition, defendant Guthart has served as a director of the Company since 2009. Defendant Guthart joined the Company in 1996. Upon information and belief, defendant Guthart is a citizen of

California.

32. Defendant Marshall L. Mohr ("Mohr") has served as the Company's Senior Vice President and Chief Financial Officer ("CFO") since March 2006. Upon information and belief, defendant Mohr is a citizen of California.

33. Defendant Lonnie M. Smith ("Smith") served as the Company's CEO from June 1997 to January 2010. From January 2010 until at least 2013, defendant Smith continued to serve as an executive of the Company. In addition, defendant Smith has served as Chairman of the Board since 1997. Upon information and belief, defendant Smith is a citizen of California.

34. Defendant David J. Rosa ("Rosa") has served as the Company's Senior Vice President, Scientific Affairs since 2013. According to the Company's public filings, Rosa has held "leadership positions" in engineering, clinical development, marketing and product development since joining the Company in 1996. Upon information and belief, defendant Rosa is a citizen of California.

35. Defendant Mark J. Meltzer ("Meltzer") has served as the Company's Senior Vice President, General Counsel and Chief Compliance Officer since 2007. Upon information and belief, defendant Meltzer is a citizen of California.

36. Defendant Jerome J. McNamara ("McNamara") has served as the Company's Executive Vice President, Worldwide Sales and Marketing since 2007. Upon information and belief, defendant McNamara is a citizen of California.

37. Defendant Augusto V. Castello ("Castello") has served as the Company's Senior Vice President, Product Operations since 2009. Upon information and belief, defendant Castello is a citizen of California.

38. Defendant Salvatore J. Brogna ("Brogna") has served as the Company's Senior Vice President, Product Development since 2010. Previously, defendant Brogna served as the

Company's Vice President, Engineering from 2005 until 2010, and as the Company's Director, Mechanical Engineering from 1999 until 2005. Upon information and belief, defendant Brogna is a citizen of California.

39. Defendant Colin Morales ("Morales") has served as the Company's Senior Vice President, Manufacturing and Service Operations since 2010. Morales previously served as the Company's Vice President of the Customer Support Group from July 2005 until 2010, and as Director of Field Service from 1999 until 2005. Upon information and belief, defendant Morales is a citizen of California.

40. Defendant Craig H. Barratt ("Barratt") has served as a director of the Company since April 2011. Upon information and belief, defendant Barratt is a citizen of California.

41. Defendant Eric H. Halvorson ("Halvorson") has served as a director of the Company since June 2003. In addition, defendant Halvorson served as a member of the Board's Audit Committee (the "Audit Committee") during the Relevant Period. Upon information and belief, defendant Halvorson is a citizen of California.

42. Defendant Amal M. Johnson ("Johnson") has served as a director of the Company since April 2010. Upon information and belief, defendant Johnson is a citizen of California.

43. Defendant Alan J. Levy ("Levy") has served as a director of the Company since 2000. Upon information and belief, defendant Levy is a citizen of Washington.

44. Defendant Floyd D. Loop ("Loop") has served as a director of the Company since 2005. Upon information and belief, defendant Loop is a citizen of Ohio.

45. Defendant Mark J. Rubash ("Rubash") has served as a director of the Company since October 2007. In addition, defendant Rubash served as the Chairman of the Audit Committee during the Relevant Period. Upon information and belief, defendant Rubash is a citizen of California.

46. Defendant George Stalk Jr. ("Stalk") has served as a director of the Company since 2007. In addition, defendant Stalk served as a member of the Audit Committee during the Relevant Period. Upon information and belief, defendant Stalk is a citizen of Canada.

47. Collectively, defendants Guthart, Mohr, Smith, Rosa, Meltzer, McNamara, Castello, Brogna, Morales, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk shall be collectively referred to herein as the "Defendants."

48. Collectively, defendants Halvorson, Rubash, and Stalk shall be collectively referred to herein as "Audit Committee Defendants."

49. Collectively, defendants Smith, Guthart, Mohr, Rosa, Meltzer, McNamara, Castello, Brogna, Morales, Halvorson and Levy shall be collectively referred to herein as "Insider Selling Defendants."

DEFENDANTS' DUTIES

50. By reason of their positions as officers, directors, and/or fiduciaries of Intuitive and because of their ability to control the business and corporate affairs of Intuitive, Defendants owed Intuitive and its shareholders fiduciary obligations of good faith, loyalty, and candor, and were and are required to use their utmost ability to control and manage Intuitive in a fair, just, honest, and equitable manner. Defendants were and are required to act in furtherance of the best interests of Intuitive and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of the Company owes to Intuitive and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

51. Defendants, because of their positions of control and authority as directors and/or officers of Intuitive, were able to and did, directly and/or indirectly, exercise control over the

wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Intuitive, each of the Defendants had knowledge of material non-public information regarding the Company.

52. To discharge their duties, the officers and directors of Intuitive were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Intuitive were required to, among other things:

a. Exercise good faith to ensure that the affairs of the Company were conducted in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

b. Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority; and

c. When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

53. The Company's Code of Business Conduct and Ethics (the "Code") applies to all directors, officers and employees, and therefore applies to the Defendants. The Code sets forth the following, in relevant part:

> Employees who possess or have access to material, non-public information gained through their work at ISI may not use that information to trade in ISI securities or the securities of another company to which the information pertains. Further, employees may not engage in any other action to take advantage of, or pass on to others (*i.e.*, "tip"), material information before its release to the public at large until three days after that information has been publicly disclosed. These restrictions also apply to

> your family members, friends, or associates, and are in addition to your obligations with respect to nonpublic information generally, as discussed above.
>
> Material nonpublic information includes any information that is not known to the general public and that a reasonable investor would consider important in a decision to buy, hold, or sell securities. Examples of such information include earnings or other financial results, new or lost contracts or products, sales results (including system sales and procedure volumes), important personnel changes, business plans, possible mergers, acquisitions, or joint ventures, important litigation developments, and important regulatory, judicial or legislative actions.
>
> Employees who possess or have access to material inside information relating to quarterly or annual financial results are prohibited from trading in ISI securities during certain "blackout" periods. Additional restrictions on trading or speculating in ISI stock apply to certain officers and selected employees as determined by the CFO.
>
> The law and Company policy do permit employees to trade in ISI securities regardless of their awareness of material nonpublic information if the transaction is made pursuant to a pre-arranged trading plan that was established in compliance with applicable law and was entered into when the person was not in possession of material nonpublic information.

54. Pursuant to the Audit Committee's Charter, the members of the Audit Committee are required, *inter alia*, to:

a. Oversee the integrity of the Company's financial statements, accounting and financial reporting processes and financial statement audits;

b. Oversee the Company's compliance with legal and regulatory requirements related to financial reporting;

c. Meet with management and the independent auditor to review and discuss the Company's annual financial statements and quarterly financial statements (prior to the Company's Form 10-K or 10-Q filings or release of earnings), as well as all internal control reports (or summaries thereof);

d. Review other relevant reports or financial information submitted by the Company to any governmental body or the public, including Form 10-K, Form 10-Q, proxy statements, management certifications as required by the

Sarbanes-Oxley Act of 2002 ("SOX Certifications"), and relevant reports rendered by the independent auditor (or summaries thereof);

e. Recommend to the Board whether the financial statements should be included in the annual report on Form 10-K;

f. Discuss earnings press releases, including the type and presentation of information, paying particular attention to any pro forma or adjusted non-GAAP information;

g. Discuss financial information and earnings guidance provided to analysts and ratings agencies;

h. Review the integrity of the Company's financial reporting processes (both internal and external), and the internal control structure (including disclosure controls and procedures and internal control over financial reporting);

i. Review major issues regarding accounting principles and financial statement presentations, including any significant changes in the Company's selection or application of accounting principles; major issues as to the adequacy of the Company's internal controls; and any special audit steps adopted in light of material control deficiencies;

j. Review any material reports or inquiries received from regulators, governmental agencies or employees that raise material issues regarding the Company's financial statements and accounting or compliance policies; and

k. Discuss policies with respect to risk assessment and risk management, including appropriate guidelines and policies to govern the process, as well as the Company's major financial risk exposures and the steps management has undertaken to control them.

SUBSTANTIVE ALLEGATIONS

A. Background

55. According to its public filings, Intuitive, based in Sunnyvale, California, designs, manufactures, and markets da Vinci surgical systems, and related instruments and accessories, EndoWrist instruments consisting of forceps, scissors, electrocautery, scalpels, and other surgical tools, and EndoWrist Stapler 45 instrument, a wristed stapling instrument intended for resection, transaction, and/or creation of, such as sterile drapes, 3-D stereo endoscopes, camera heads, light guides, and other items that are used in conjunction with the da Vinci surgical system.

56. Intuitive Surgical has been the market leader in robotic-controlled surgery devices before and during the Relevant Period. The Company conducted an initial public offering in 2000 when the FDA approved its sole product, the da Vinci Surgical System, for laparoscopic surgery. This initial approval was limited to certain procedures, such as gallbladder and gastroesophageal surgery. In the years following, the FDA approved da Vinci for additional treatments, including thoracoscopic (chest) surgery, cardiac procedures performed with adjunctive incisions, as well as urologic, gynecologic, pediatric, and transoral otolaryngology surgeries. Intuitive now dominates the robot-surgery field as it is the only company whose system is cleared in the United States for soft tissue procedures, which include prostate and gynecological surgery.

57. As the market leader, the Company has been growing rapidly in the last few years. As of December 31, 2012, there were 2,585 da Vinci Systems installed in approximately 2,025 hospitals worldwide. The number of U.S. procedures performed with these robots grew to approximately 367,000 in 2012, up from 292,000 in 2011, and 228,000 in 2010. Total revenue rose from $1.41 billion in 2010, to $1.76 billion in 2011, and $2.18 billion in 2012. Da Vinci system sales rose from 441 da Vinci systems in 2010 to 534 in 2011 and 620 in 2012.

58. Intuitive's revenue is solely generated from the da Vinci Surgical System. In 2012,

revenues from sales of da Vinci represented about 43% of the overall revenue. Each unit costs between $1.0 and $2.3 million. The rest was generated by "recurring revenue," which included sales of da Vinci instruments and accessories (approximately $1,300 to $2,000 per procedure) and sales of da Vinci service agreements. Annual service agreements range between $100,000 and $170,000 per system. During 2012, instrument and accessory revenue contributed 41% and service revenue generated 16%.

B. Defendants Concealed Da Vinci's Defects And Performance Problems

1. Da Vinci's Monopolar Scissors Caused Severe Injuries Due To Defective Tip Covers And Arcing

59. The da Vinci Surgical System consists of several key components, including (i) an ergonomically designed console equipped with a high-definition 3-dimensional vision system where the surgeon sits while operating, (ii) a patient-side cart where the patient lays during surgery, (iii) three or four interactive robotic arms, (iv) proprietary EndoWrist® instruments that attach to the robotic arms, and (v) a hardware console, which houses the computer operating system and software that controls the robotic arms. Together, these components allow surgeons to operate by manipulating a suite of tiny computer-assisted remote control tools through a small tube inside a patient.

60. The EndoWrist Instruments include a number of endoscopic surgical parts used with da Vinci for a wide range of surgical tasks, such as tissue manipulation, suturing, cutting, coagulation, and clamping. Most instruments have an articulating design at the tips that enter the patient's body, known as a "wrist," and provide various degrees of motion that mimic the human hand and wrist-movements. Quick-release levers facilitate instrument changes during surgical procedures. The instruments also have an electronic tag that identifies each specific instrument and

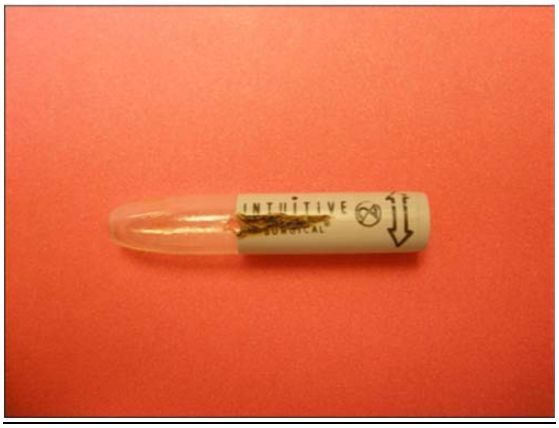
limits the number of uses so that the tag "expires" the instrument after a pre-determined number of uses.

61. The most commonly used Endowrist instrument is the Hot Shears Monopolar Curved Scissors ("Monopolar Scissors"). According to a study entitled "Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury," co-authored by Adam C. Mues, Geoffrey N. Box, and Ronney Abaza, and published in 2011 in the Journal of Urology, 24 surgeons performed 454 robotic procedures between July 2008 and January 2009, and all of the procedures involved the Monopolar Scissors. The use of the Monopolar Scissors is so prevalent because it allows doctors to both cut and cauterize tissue during surgical procedures. Cauterization occurs through the application of monopolar electricity.

62. To prevent the electricity from spreading to unwanted areas, the Monopolar Scissors requires the use of the Tip Cover, which is also sold by Intuitive. The Tip Cover is a sleeve, and consists of a silicon or flexible rubber-like material connected to a harder plastic-like tube called an altum. It is placed over the end of the Monopolar Scissors to insulate the instrument's metal parts and allow only the exposed electrode (the scissor blades) to emit electrical current to the intended area designated by the surgeon. While the intended use of the current is cauterization, when inadvertently applied to adjacent tissue the current causes harmful burns and other serious injuries.

Monopolar Scissors with Tip Cover Accessory

Damaged Tip Cover Accessory[3]



63. "The Tip Cover plays an important role in the robotic instrument" because it "serves as an insulation for the metallic segment of the EndoWrist and prevents broad dissipation of monopolar electric current," according to an article published in March 2011 by Yonsei University College of Medicine, entitled "Iliac Vein Injury Due to a Damaged Hot Shears Tip Cover During Robot Assisted Radical Prostatectomy." If the Tip Cover functions properly, the article reported, "[i]t allows safe dissection in proximity to delicate structures such as blood vessels, nerves and bowel." If the Tip Cover fails, however, electricity can escape the Monopolar Scissors and burn or harm patients. This is commonly referred to as "arcing" because a visual arc of electricity is formed from the defect in the insulated portion of the Tip Cover to another instrument or tissue. The tissue is thus burnt and injured.

64. Even more severe injuries occur when the arcing is not in the field of vision of the

[3] The images of the Monopolar Scissors and the Tip Cover Accessory were published in "Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury." Adam C. Mues, Geoffrey N. Box, and Ronney Abaza, J. of Urology 105 (2011).

surgeon and therefore remains undetected. Perforation of internal organs and blood vessels causes internal bleeding and severe injuries that are discovered days after the surgery, and only after the patient's condition has deteriorated rapidly for unknown reasons. One such patient was Sonya Melton. In an interview reported by CNBC on March 19, 2013 ("Robotic Surgery: Growing Sales, but Growing Concerns") "[Sonya Melton] said she had become so sick almost immediately after her surgery to remove uterine fibroids that she thought she was going to die. Her condition, she said, puzzled doctors so much that within days they sliced open her stomach to find out why she was in excruciating pain and had developed a full-fledged pneumonia. What they found, she said, was a perforation in her small intestine." It turns out, as CNBC reports, Melton's ureters, which carry urine from the kidneys to the bladder, had been "burned."

65. Other patients have tragically died as a result of undetected burns. As reported by *Bloomberg* on March 5, 2013, ("Robosurgery Suits Detail Injuries as Death Reports Rise"), Kimberly McCalla underwent surgery with da Vinci to treat early-stage cervical cancer on August 12, 2010. "Eleven days after the operation, she was rushed back into surgery, where doctors found a laceration of the iliac artery near the original operation….The doctors sewed the artery up, but it was too late. After two more emergency operations, Kimberly died on August 25 after suffering [] bowel damage 'incompatible with life,' according to an operative report."

66. A subsequent lawsuit filed on behalf of Ms. McCalla's estate alleged that "there had been a burn of the right external iliac artery."[4] The lawsuit also alleged that the burn to the iliac artery was sustained due to a defective device that used "monopolar energy to cut, burn and cauterize tissue," which had "inadequate insulation" thereby "allowing electrical current to pass into tissue outside of the operative field," and ultimately resulting in death to the patient.

[4] *McCalla v. Intuitive Surgical, Inc.*, No. 12-2297 (S.D.N.Y. Apr. 2, 2012), ECF. No. 1.

67. The severe injuries suffered by Sonya Melton and Kimberly McCalla as a result of monopolar current are not isolated cases. Indeed, a review of the MAUDE database shows that there was a substantial and material increase in Tip Cover related MDRs in 2011 and 2012 compared to prior years, and that there has been a corresponding increase in Tip Cover reports related specifically to arcing or burning. These injuries and defects have also resulted in a notable increase in products liability and/or personal injury lawsuits filed against Intuitive.[5]

2. The October 2011 Secret "Class II Recall" Of The Tip Covers And Other Concealed Corrective Actions

68. At least as early as October 2011, Defendants were on notice that the Tip Cover was defective, did not insulate properly, and allowed electricity to escape. One of the problems was that it was very difficult to install correctly, in part, because it required a fairly large amount of force to fit the rubber-sleeve Tip Cover over the instrument.[6] Because the Tip Covers were fragile, when installed incorrectly or after the use of force, they were easily damaged or torn.

69. On October 10, 2011, Defendants caused Intuitive to send out a letter to hospitals that used da Vinci systems. The letter corrected the instructions for proper use for Tip Covers and sought to prevent tears and ensure that Tip Covers functioned properly. Defendants caused Intuitive to send the letter in response to complaints and MDRs reporting arcing through damaged Tip Covers that had caused patient injury, but did not distribute the letter publicly.

70. The FDA Warning Letter issued in July 2013 subsequently reported that Intuitive's

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[5] It has been alleged that an analysis of lawsuits filed against Intuitive between March 2010 and August 2013 reveals there were at least 25 such lawsuits, 18 of which included allegations related to insufficient insulation allowing monopolar current to pass onto patient tissue, resulting in inadvertent burns and other injury.

[6] Diana C.W. Friedman, Thomas S. Lendvay, Blake Hannaford, Instrument Failures for the da Vinci Surgical System: a Food and Drug Administration MAUDE Database Study, Surgical Endoscopy (2013) 27:1507.

October 2011 letter had constituted a "Class II Recall." The FDA Warning Letter found that, in violation of FDA regulations, Intuitive did not report this recall to the San Francisco District Recall Coordinator ("SFDRC"), the designated FDA office to receive such reports. Defendants concealed this corrective action from the FDA as part of a broader concerted effort to bury and minimize any negative reports about da Vinci.

71. Defendants also caused the Company to conceal from the FDA other serious corrective actions. On October 13, 2011, Defendants caused Intuitive to send out another letter notifying da Vinci hospitals that da Vinci was not cleared for thyroidectomy procedures – *i.e.*, the surgical removal of all or part of the thyroid gland. Defendants had previously caused Intuitive to market da Vinci for these procedures and profited from the revenues generated. Defendants also caused Intuitive not to report this letter to the SFDRC. The FDA, again, later classified Intuitive's corrective action taken on October 13, 2011 as a "Class II Recall."

72. On October 17, 2011, Defendants caused Intuitive to send yet a third corrective letter to da Vinci hospitals with information for inspecting instrument cannulas – *i.e.*, a hollow rigid tube inserted into the body that allows the instruments on the robotic arms to access patients' anatomy through the small incisions. Damaged Tip Covers due to defective cannulas was identified in the Form 483 as "one of the root causes" for arcing that resulted in patient injuries. This action was also not reported to the SFDRC. Again, the FDA later classified Intuitive's corrective action taken on October 13, 2011 as a "Class II Recall."

C. Defendants Violated FDA Regulations By Concealing Modifications To The Tip Covers

73. Pursuant to § 519(g) of the FDCA, 21 U.S.C. § 360i(g), and 21 C.F.R. § 806 of the Reports of Corrections and Removals regulation, companies such as Intuitive are required to provide promptly to the FDA a written report "of any correction or removal of a device initiated by

such manufacturer or importer if the correction or removal was initiated [to] . . . reduce a risk to health posed by the device." 21 C.F.R. § 806.10(a). The regulation defines a "[c]orrection" as "the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d). A "[r]isk to health" is defined as "(1) [a] reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) [t]hat use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote." 21 C.F.R. § 806.2(j). "Removal" means "the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection." 21 C.F.R. § 806.2(i).

D. Medical Device Reports Also Showed That Defendants Were On Notice Of The Defects In The Tip Covers For Years

74. The main mechanism through which the FDA is apprised of health risks from medical devices, including da Vinci, are MDRs. The purpose of MDRs is "to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use." 21 C.F.R. § 803.1.

75. MDRs are therefore critical components of the FDA's ability to monitor a device's performance and determine if further FDA actions are necessary, including inspections of facilities and post-market studies. MDRs filed with the FDA are compiled in the FDA's MAUDE database.

76. It has been alleged that an analysis of the MAUDE database, along with the results, show that there had been a substantial and material increase in Tip Cover-related MDRs in 2011 and 2012 compared to prior years. (These MDRs reference Tip Cover model number 400180).

77. The number of Tip Cover-related MDRs for each year between 2007 and 2010 were,

respectively, 19, 60, 77, and 68. In 2011 and 2012, the MDRs increased to 117 and 104. Accordingly, the annual average between these two periods nearly doubled, from 56 in the 2007-2010 period to 110.5 in 2011 and 2012.

78. Of these MDRs, the average annual Tip Cover incidence that related to arcing or burning more than doubled when comparing the same periods. Between 2007 and 2010, there were, respectively, 2, 24, 14, and 22 such MDRs. In 2011 and 2012, those MDRs increased to 34 and 38, respectively. Accordingly, the annual average also more than doubled, from 15.5 between 2007 and 2010, to 36 between 2011 and 2012.

79. More recently, issuance of MDRs related to Monopolar Scissors and Tip Covers (model numbers 400180, 400179, 420179) have continued their steep upward trajectory. In 2013 there has been a 54% increase in reported MDRs related to Monopolar Scissors and Tip Covers, compared to 2012, from 128 in 2012 to 197 in 2013.

E. Defendants Caused the Company to Systematically Conceal And Underreport Medical Device Reports To The FDA

1. MDRs Reporting Procedures to the FDA Are Strictly Regulated

80. Strict regulations promulgated by the FDA govern MDR reporting procedures, which rely primarily on the manufacturer's reporting obligations since approximately 94% of the MDRs received by the FDA are reported by the manufacturer.[7] Pursuant to these regulations, when an adverse event related to a serious injury occurs, user facilities, *e.g.* hospitals, are required to report these injuries to the manufacturer: "whenever a device user facility [e.g. hospitals] receives or otherwise becomes aware of … information that reasonably suggests that a device has or **may have**

[7] "Adverse Event Reporting for Medical Devices," Department of Health and Human Services, Office of the Inspector General, Oct. 2009 (finding that 94% of medical device adverse event reports filed with the FDA were submitted by device manufacturers in 2007) https://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf.

caused or contributed to … a serious injury to a patient of the facility… the facility shall … report the information … to the manufacturer." 21 U.S.C. § 360i(b)(1)(B) (emphasis supplied); *see also* 21 C.F.R. §§ 803.30, 803.50.

81. Manufacturers must then report to the FDA "no later than 30 calendar days after the day that [the manufacturers] receive or otherwise become aware of information, from any source, that reasonably suggests that a device that [the manufacturers] market: (1**) [m]ay have caused or contributed to a death or serious injury**; or (2) [h]as malfunctioned and this device or a similar device that [the manufacturers] market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a).

82. The obligations of the manufacturers, such as Intuitive, are not limited to merely reporting adverse events, but also include the obligation to further investigate and understand the underlying causes. Manufacturers "are also responsible for conducting an investigation of each event and evaluating the cause of the event." 21 C.F.R. § 803.50(b). If the original report is incomplete, the regulations also require manufacturers to "provide a statement explaining why this information was incomplete and the steps [taken] to obtain the information." *Id.* And if the manufacturer later obtains information not available at the time it filed the initial report, the manufacturer must file a supplemental report with the new information. *Id.*

B. Defendants Caused the Company to Systematically Violate FDA Reporting Regulations

83. Defendants caused the Company to brazenly violate these FDA regulations by minimizing and underreporting serious injuries and defects arising from da Vinci. A medical journal study of Intuitive's reporting practices to the FDA concluded that the Company underreported robotic surgery complications between January 2000 and August 2012, and highlighted facts that strongly suggest that strongly support that reasonable inference that

Defendants did so intentionally. The study ("Underreporting of Robotic Surgery Complications") was published in the *Journal for Healthcare Quality* in September 2013.[8] The purpose of the study was to test whether robotic surgery complications may be more common than represented in FDA adverse event reports.

84. The study cross referenced MDRs in the MAUDE database with legal documents retrieved from LexisNexis and PACER. Of the 70 events found in the legal databases, eight, or more than 10%, had not been reported to the FDA, including deaths, perforations, and severe injuries. In five of the cases, no report was ever filed with the FDA. In two cases, the MDRs were filed only after *The Wall Street Journal* ("*WSJ*") and *Reuters* reported the story – one of the MDRs "disputes the death" and only acknowledged that the patient suffered nerve damage. In a separate instance, even though an Intuitive representative had been present during the surgery and witnessed the patient's death, Defendants caused Intuitive still not to report it to the FDA.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS

A. False and Misleading Statements in SEC Filings

85. On February 6, 2012, Defendants caused the Company to file its Form 10-K for the year ending December 31, 2011 (the "2011 Form 10-K"). The 2011 Form 10-K was signed by defendants Guthart, Mohr, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk, and stated, in relevant part:

(a) "[w]e believe that this new generation of surgery, which we call da Vinci Surgery, combines the benefits of minimally invasive surgery (MIS) for patients with the ease of use, precision and dexterity of open surgery;" and

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[8] Michol A. Cooper, Andrew Ibrahim, Heather Lyu and Martin A. Makary, Underreporting of Robotic Surgery Complications, J. for Healthcare Quality (2013).

(b) "The da Vinci Surgical System enables surgeons to extend the benefits of MIS to many patients typically receiving open surgery by using computational, robotic and imaging technologies to overcome many of the limitations of conventional minimally invasive surgery."

86. The 2011 Form 10-K also contained SOX Certifications signed by defendants Guthart and Mohr. The SOX Certifications set forth:

I, [Gary S. Guthart/Marshall L. Mohr], certify that:

1. I have reviewed this annual report on Form 10-K of Intuitive Surgical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

> d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
>
> 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
>
> a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
>
> b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.
>
> * * *
>
> Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Intuitive Surgical, Inc. (the "Company") hereby certifies, to such officer's knowledge, that:
>
> (i) the accompanying Annual Report on Form 10-K of the Company for the period ended December 31, 2011 (the " Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
>
> (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

87. In touting the benefits of the "da Vinci Surgical System," Defendants concealed that far from "extend[ing] the benefits of MIS," da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects resulting in (i) Defendants causing Intuitive to institute three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (ii) the issuance of 508 MDRs and complaints reporting material health risks to patients as a result of da Vinci in 2011 alone, including ten death-related reports and a material increase in Tip Cover-related MDRs in 2011 compared to prior years; and (iii) at least four personal injury and/or product

liability lawsuits filed against Intuitive between March 18, 2010 and December 31, 2011.

88. In the 2011 Form 10-K, Defendants also warned against potential defects even while they were on notice that da Vinci exhibited, and had exhibited for some time, dangerous defects:

> If defects are discovered in our products, we may incur additional unforeseen costs, hospitals may not purchase our products and our reputation may suffer. . . . . Because our products are designed to be used to perform complex surgical procedures, we expect that our customers will have an increased sensitivity to such defects. In the past, we have voluntarily recalled certain products as a result of performance problems. We cannot assure that our products will not experience component aging, errors or performance problems in the future.
>
> * * *
>
> "There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall."

89. The 2011 Form 10-K was materially false and misleading because it failed to disclose that (i) da Vinci posed a present material health risk to patients; (ii) da Vinci already had known defects; (iii) Defendants had caused Intuitive to violate FDA regulations by failing to report to the FDA corrective actions taken by Intuitive to reduce health risks posed by da Vinci; and (iv) Defendants had already undertaken three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA Warning Letter. According to the FDA Warning Letter and Form 483, Defendants had undertaken these recalls after receiving over 166 complaints and 87 MDRs since July 2009, the vast majority of which concerned the Tip Covers. The FDA Warning Letter further determined that Intuitive ignored design deficiencies in violation of CGMP even though it was aware of patient injuries in 2010 and 2011 due to the intraoperative cleaning of Monopolar Scissors.

90. Intuitive's 2011 Form 10-K further set forth the specific regulations the Company was required to follow in connection with da Vinci and its accessories, including, but not limited to: (i) "the QSR, which requires manufacturers to follow elaborate design, testing, control documentation and other quality assurance procedures during the manufacturing process;" (ii) "the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their

device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur" (21 C.F.R. § 803.50); and (iii) "the reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FDCA [Federal Food, Drug, and Cosmetic Act] that may pose a risk to health" (21 C.F.R. § 806.10).

(a) Defendants further highlighted the severe penalties that it risked for non-compliance with these regulations:

> We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of enforcement actions, ranging from a regulatory letter to a public Warning Letter to more severe civil and criminal sanctions including the seizure of our products and equipment or ban on the import or export of our products. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.
>
> * * *
>
> The QSR also requires maintenance of extensive records which demonstrate compliance with FDA regulation, the manufacturer's own procedures, specifications and testing as well as distribution and postmarket experience. Compliance with the QSR is necessary to receive FDA 510(k) clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings in the United States.

91. The 2011 Form 10-K also acknowledged that the Company was subject to "extensive and rigorous regulation by the FDA" with which it kept current and in compliance: "Our products and operations are subject to extensive and rigorous regulation by the FDA, the State of California and countries or regions in which we market our products …. We must continually keep abreast of these standards and requirements and integrate compliance to these with the development and regulatory documentation for our products."

92. At the time this 2011 Form 10-K was filed, these statements were materially false and misleading because they failed to disclose that according to the FDA Warning Letter,

Defendants had already systematically violated FDA regulations by: (i) secretly issuing corrections starting in October 2011 related to defects without properly reporting those corrections to the FDA, in violation of 21 C.F.R. § 806.10; and (ii) by significantly deviating from the Current Good Manufacturing Practice (CGMP) requirements for devices, as set forth in the Quality System regulation (21 C.F.R. § 820).

93. Defendants' statements were further materially false and misleading because they failed to disclose Defendants' failure to report, or timely report, adverse events through the MDR mechanism, as required by 21 C.F.R. §803.50.

94. In addition, the 2011 Form 10-K represented that:

> Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of our products were to cause injury or death. There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall. Any weaknesses in training and services associated with our products may also be subject to product liability lawsuits. . . .If a patient is harmed during a da Vinci surgical procedure, even in the absence of any alleged system malfunction or defect, we can be exposed to negligence claims based on alleged inadequacies in our surgeon training, our training of Intuitive personnel, or in our proctoring programs. A negligence claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Negligence claims have been made against us in the past.

95. The 2011 Form 10-K also stated that, "[f]rom time to time, we may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business."

96. These statements were materially false and misleading because they failed to disclose that:

(a) as of February 6, 2012, at least four lawsuits alleged that patients had been harmed due to da Vinci, and

(b) it was highly likely that additional suits would be filed in the future because (i) da

Vinci posed a material health risk to patients; (ii) Defendants had taken corrective actions to reduce health risks in October 2011, but hundreds of thousands of surgeries had been performed with da Vinci already before that date; (iii) there had been a substantial number of MDRs and complaints reporting material health risks to patients; and (iv) Defendants had failed to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

97. The 2011 Form 10-K also reported 2011 financial results as follows: (i) Total revenue of $1,757.3 million for 2011 had increased by 24% and 34% during the years ended December 31, 2011 and 2010, respectively, compared to the same periods in 2010 and 2009, reflecting "continued adoption of da Vinci"; (ii) "Approximately 360,000 da Vinci procedures were performed during the year ended December 31, 2011, up approximately 29% from last year"; (iii) "System revenue increased 18% to $777.8 million during the year ended December 31, 2011 from $660.3 million during the year ended December 31, 2010"; and (iv) Intuitive sold "534 da Vinci Surgical Systems during the year ended December 31, 2011, compared with 441for the year ended December 31, 2010."

98. These financial results reported in the 2011 Form 10-K were materially false and misleading because Defendants failed to disclose that da Vinci, which was solely responsible for the Company's sales and revenue growth, would be materially impacted by the following: (i) da Vinci posed a material health risk to patients; (ii) Defendants had violated FDA regulations by failing to properly report corrective actions taken by Intuitive to reduce health risks posed by da Vinci; (iii) Defendants had instituted three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (iv) Intuitive was in violation of CGMP, in part, due to critical missing design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (v) there had been a substantial number of MDRs and complaints reporting material health risks to patients, all of which when disclosed would adversely impact the Company's business; and (vi) Defendants had failed to

report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

99. On April 17, 2012, Defendants caused the Company to file with the SEC a Form 8-K attaching a press release announcing the Company's 1Q 2012 results (the "April 17th Press Release"). Defendant Guthart commented as follows: "In the first quarter, we are pleased with the growing use of da Vinci, the acceptance of our new products and the financial performance that follows."

100. The April 17th Press Release also reported that (i) first quarter revenues were $495 million, which reflected an increase of 28% compared to the first quarter of 2011, and "revenue growth was driven by continued robotic procedure adoption and higher da Vinci Surgical System sales"; (ii) "[p]rocedure growth of approximately 29% primarily reflects higher US gynecologic procedures, US general surgery procedures and international urologic procedures"; and (iii) first quarter 2012 system revenues totaled $206.6 million compared to $167.1 million in first quarter of 2011.

101. During the April 17, 2012 Q1 2012 earnings release conference call (the "April 17th Earnings Call") with investors, defendant Guthart reported that Intuitive had "sold 140 da Vinci Surgical Systems, up from 120 during the first quarter of last year," and that "[t]otal revenue was $495 million, up 28% over last year." Defendant Guthart further stated that "[w]ith regard to procedures, we experienced strong growth in general surgery and gynecology, leading to year-over-year procedure growth of approximately 29%."

102. Defendants' statements in the April 17th Press Release and April 17th Earnings Call were materially false and misleading because Defendants failed to disclose that da Vinci, which was solely responsible for Intuitive's sales and revenue growth, would be materially impacted by the following: (i) da Vinci posed a material health risk to patients; (ii) Defendants had violated FDA

regulations by failing to properly report its corrective actions to reduce health risks posed by da Vinci; (iii) Defendants had instituted three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (iv) Defendants had caused Intuitive to be in violation of CGMP, in part, due to critical missing design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (v) there had been a substantial number of MDRs and complaints reporting material health risks to patients, all of which when disclosed would adversely impact the Company's business; and (vi) Defendants had failed to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

103. On April 19, 2012, Defendants caused the Company to file its first quarter Form 10-Q for the period ending March 31, 2012 (the "1Q12 Form 10-Q"), which was signed by defendant Mohr. The 1Q12 Form 10-Q also contained SOX Certifications, signed by defendants Guthart and Mohr, which were substantially similar to those set forth above.

104. The 1Q12 Form 10-Q detailed that da Vinci surgery represents "a new generation of surgery" that "combines the benefits of minimally invasive surgery (MIS) for patients with the ease of use, precision and dexterity of open surgery." In touting the benefits of "da Vinci Surgery," Defendants concealed that far from "combin[ing] the benefits of [MIS]" (including shorter recovery times and fewer complications) with those of open surgery, da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects, resulting in (i) Defendants instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (ii) the issuance of a substantial number of MDRs and complaints reporting material health risks to patients as a result of da Vinci, including eight death-related reports in the three month period between December 31, 2011 and March 31, 2012; and (iii) at least five personal injury and/or product liability lawsuits filed against Intuitive between March 18, 2010 and March 31, 2012.

105. The 1Q12 Form 10-Q also stated "[t]here have been no changes to the Risk Factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011." The risk factors in the 2011 Form 10-K included warnings concerning possible product defects and their potential impact, possible "performance problems in the future," and the "possibility that defects in the design or manufacture of our products might necessitate a product recall."

106. The 1Q12 Form 10-Q representations were materially false and misleading because they failed to disclose that (i) da Vinci posed a material health risk to patients; (ii) da Vinci already had known defects; (iii) Intuitive had violated FDA regulations by failing to report to the FDA corrective actions taken by Intuitive to reduce health risks posed by da Vinci; (iv) Defendants had failed to report, or timely report, adverse events through the MDR mechanism, as required by 21 C.F.R. § 803.50; (v) Intuitive had violated Current Good Manufacturing Practice (CGMP) requirements, as set forth in the Quality System regulation (21 C.F.R. § 820); and (vi) Intuitive had already undertaken three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA in its Warning Letter. According to the FDA Warning Letter and Form 483, Intuitive had undertaken these recalls after receiving over 166 complaints and 87 MDRs since July 2009, the vast majority of which concerned the Tip Covers. The FDA Warning Letter further determined that Intuitive ignored design deficiencies in violation of CGMP even though it was aware of patient injuries in 2010 and 2011 due to the intraoperative cleaning of Monopolar Scissors.

107. The 1Q12 Form 10-Q contained a section entitled "Risk Factors," which stated that there had been "no changes to the Risk Factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011," filed on February 6, 2012. In Intuitive's 2011 Form 10-K, Defendants had represented that "the use of our products could result in product liability and negligence claims that could be expensive, divert management's attention and harm our business."

The 2011 Form 10-K had further stated:

> Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of our products were to cause injury or death. There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall. Any weaknesses in training and services associated with our products may also be subject to product liability lawsuits. Although we maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. Particularly as sales of our products increase, we may be unable to maintain product liability insurance in the future at satisfactory rates or in adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Product liability claims have been made against our company in the past. A product liability or negligence claim or any product recalls could also harm our reputation or result in a decline in revenues.

108. The 1Q 2012 Form 10-Q also represented that "[f]rom time to time, we may be involved in a variety of claims . . . relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business."

109. These statements were materially false and misleading because they failed to disclose that:

(a) as of April 19, 2012, at least seven lawsuits were filed against Intuitive concerning da Vinci defects, at least two of which alleged that patients had been harmed due to arcing caused by Microcracks/insufficient insulation - Monopolar current; and

(b) it was highly likely that additional suits would be filed in the future because (i) da Vinci posed a material health risk to patients; (ii) Defendants had taken corrective actions to reduce health risks in October 2011, but hundreds of thousands of surgeries had been performed with da Vinci already before that date; (iii) Defendants had caused Intuitive to be in violation of CGMP, in part, due to missing critical design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (iv) there had been a substantial number of MDRs and complaints reporting material health risks to patients; and (v) Defendants had failed to report, or timely report,

complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

110. The 1Q 2012 Form 10-Q reiterated the financial results announced in the April 17th Press Release and April 17th Earnings Call. These financial results were materially false and misleading, as set forth above.

111. On July 19, 2012, Defendants caused the Company to file with the SEC a Form 8-K attaching a press release announcing the Company's 2Q 2012 financial results (the "July 19th Press Release"). Defendant Guthart commented that the "solid second quarter revenue and earnings performance is the result of robust US gynecologic and general surgery procedure growth offset by pressure in Europe and US prostatectomy." The July 19th Press Release also reported that total revenue for 2Q 2012 of $537 million was up 26% compared with $426 million for 2Q 2011, which was "driven by continued adoption of da Vinci surgery procedures and higher da Vinci Surgical System sales."

112. Defendants made similarly materially false and misleading statements on the July 19, 2012, earnings call ("July 19th Earnings Call"):

(a) According to defendant Guthart, "our team has delivered a solid performance, driven by robust growth in both our US gynecology business and our emerging general surgery business." He also added that "for 2012, Intuitive is focused on . . . continuing our growth in gynecology and urology worldwide, through outstanding execution in the field."

(b) As to quantitative results, defendant Guthart reported that, "[p]rocedures grew approximately 26% over the second quarter of 2011. We sold 150 da Vinci Surgical Systems, up from 129 during the second quarter of last year. Total revenue was $537 million; up 26% over last year."

(c) Defendant Mohr also reported second quarter 2012 systems revenue of "$229 million, increased 23% compared with $187 million for the second quarter of 2011."

113. Defendants' statements in the July 19, 2012 July 19th Press Release and July 19th Earnings Call were materially false and misleading because Defendants failed to disclose that da Vinci, which was solely responsible for the Company's sales and revenue growth, would be materially impacted by the following: (i) da Vinci posed a material health risk to patients; (ii) Defendants had violated FDA regulations by failing to properly report corrective actions it took to reduce health risks posed by da Vinci; (iii) Defendants had instituted three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (iv) Defendants had caused Intuitive to be in violation of CGMP, in part, due to critical missing design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (v) there had been a substantial number of MDRs and complaints reporting material health risks to patients, all of which when disclosed would adversely impact Intuitive's business; and (vi) Defendants had failed to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

114. On July 23, 2012, Defendants caused the Company to file its second quarter Form 10-Q for the period ending June 30, 2012 (the "2Q12 Form 10-Q"), which was signed by defendant Mohr. The 2Q12 Form 10-Q also contained SOX Certifications, signed by defendants Guthart and Mohr, which were substantially similar to those set forth above. In the 2Q12 Form 10-Q, Defendants repeated the representations from Intuitive's 1Q12 Form 10-Q, describing, inter alia, the da Vinci as a "a new generation of surgery" which "combines the benefits of [MIS]" with those of open surgery.

115. In touting the benefits of "da Vinci Surgery," Defendants concealed that far from "combin[ing] the benefits of [MIS]" (including shorter recovery times and fewer complications) with those of open surgery, da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects present in da Vinci, resulting in (i) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (ii) the

issuance of a substantial number of MDRs and complaints reporting material health risks to patients as a result of da Vinci, including 11 death-related reports in the three months between March 31, 2012 and June 30, 2012; and (iii) at least eight personal injury and/or product liability lawsuits against Intuitive filed between March 18, 2010 and June 30, 2012, at least three of which allege injuries associated with Microcracks/insufficient insulation - Monopolar current.

116. The 2Q12 Form 10-Q also repeated "[t]here have been no changes to the Risk Factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011." The risk factors in the 2011 Form 10-K included warnings concerning possible product defects and their potential impact, possible "performance problems in the future," and the "possibility that defects in the design or manufacture of our products might necessitate a product recall."

117. The 2Q12 Form 10-Q representations were materially false and misleading because they failed to disclose that (i) da Vinci posed a material health risk to patients; (ii) da Vinci already had known defects; (iii) Defendants had violated FDA regulations by failing to report to the FDA corrective actions taken by Intuitive to reduce health risks posed by da Vinci; (iv) Defendants had failed to report, or timely report, adverse events through the MDR mechanism, as required by 21 C.F.R. § 803.50; (v) Defendants had violated Current Good Manufacturing Practice (CGMP) requirements, as set forth in the Quality System regulation (21 C.F.R. § 820); and (vi) Intuitive had already undertaken three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA in its Warning Letter. According to the FDA Warning Letter and Form 483, Intuitive had undertaken these recalls after receiving over 166 complaints and 87 MDRs since July 2009, the vast majority of which concerned the Tip Covers. The FDA Warning Letter further determined that Intuitive ignored design deficiencies in violation of CGMP even though it was aware of patient injuries in 2010 and 2011 due to the

intraoperative cleaning of Monopolar Scissors.

118. In addition, the Form 10-Q contained a section entitled "Risk Factors," which stated that there had been "no changes to the Risk Factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011," filed on February 6, 2012. In Intuitive's 2011 Form 10-K Defendants had represented that "the use of our products could result in product liability and negligence claims that could be expensive, divert management's attention and harm our business." The Form 10-K had further stated:

> Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of our products were to cause injury or death. There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall. Any weaknesses in training and services associated with our products may also be subject to product liability lawsuits. Although we maintain product liability insurance, the coverage limits of these policies may not be adequate to cover future claims. Particularly as sales of our products increase, we may be unable to maintain product liability insurance in the future at satisfactory rates or in adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Product liability claims have been made against our company in the past. A product liability or negligence claim or any product recalls could also harm our reputation or result in a decline in revenues.

119. The 2Q 2012 Form 10-Q also represented that "[f]rom time to time, we may be involved in a variety of claims . . . relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business."

120. These statements were materially false and misleading because they failed to disclose that:

(a) as of July 23, 2012, at least ten lawsuits had been filed against Intuitive concerning da Vinci defects, including at least four of which alleged that patients had been harmed due to arcing caused by Microcracks/insufficient insulation - Monopolar current; and

(b) it was highly likely that additional suits would be filed in the future because (i) da

Vinci posed a material health risk to patients; (ii) Defendants had taken corrective actions to reduce health risks in October 2011, but hundreds of thousands of surgeries had been performed with da Vinci already before that date; (iii) Defendants had caused Intuitive to be in violation of CGMP, in part, due to missing critical design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (iv) there had been a substantial number of MDRs and complaints reporting material health risks to patients; and (vi) Defendants had failed to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

121. The 2Q 2012 Form 10-Q reiterated the financial results announced in the July 19th Press Release and the July 19th Earnings Call. These financial results were materially false and misleading.

122. On October 16, 2012, Defendants caused the Company to file with the SEC a Form 8-K attaching a press release announcing the Company's financial results for Q3 2012 (the "October 16th Press Release"). Defendant Guthart stated in the press release that "acceptance of da Vinci general and gynecologic surgery continues to grow." The release also reported that, (i) total revenues had reached $538 million for Q3 2012 compared to $447 million for Q3 2011; (ii) "[t]hird quarter of 2012 revenue growth was driven by continued adoption of da Vinci surgery procedures and higher da Vinci Surgical System sales;" and (iii) "procedure growth of approximately 22% reflected US gynecologic and general surgery growth, partially offset by a decline in US prostatectomy procedures and slower growth in European practices."

123. On the October 16, 2012 Q3 2012 earnings call (the "October 16th Earnings Call"), Defendants made similarly misleading statements:

(a) Defendant Guthart stated that "acceptance of da Vinci surgery in general and gynecologic surgery continues to grow in complex cancer procedures, benign procedures, and in single-port robotic surgery."

(b) With regard to financial results, defendant Mohr stated that,

> Our third-quarter revenue was $538 million, up 20% compared with $447 million for the third quarter of 2011, and up slightly compared to the $536 million last quarter. Third-quarter revenues by product category were as follows. Thirdquarter instrument accessory revenue was $218 million, up 24% compared with $176 million for the third quarter of 2011, and down 3% compared with $224 million in the second quarter of 2012. The year-over-year increase in I&A was driven by procedure growth of approximately 22% in sales of our new instrument and accessory products, including Single-Site, Vessel Sealer and Firefly. The year-over-year procedure growth was led by US gynecologic procedures and US general surgery growth, partially offset by lower growth in Europe and a decrease in US dVP's.

(c) Defendant Mohr summarized the first nine months of 2012 results:

> Procedures grew by 25%. Total revenue was $1,570,000,000, up 25% compared with $1,261,000,000 last year. The revenue increase included recurring revenue growth of 27% and an increase in systems revenue of 21%. Also according to Defendant Mohr, systems revenue for third quarter 2012 totaled $232 million, compared with $199 million for third quarter of 2011.

124. Defendants' statements in the October 16th Press Release and October 16th Earnings Call were materially false and misleading because Defendants failed to disclose that da Vinci, which was solely responsible for Intuitive's sales and revenue growth, would be materially impacted by the following: (i) da Vinci posed a material health risk to patients; (ii) Defendants had violated FDA regulations by failing to properly report corrective actions it took to reduce health risks posed by da Vinci; (iii) Defendants had instituted three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (iv) Defendants had caused Intuitive to be in violation of CGMP, in part, due to missing critical design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (v) there had been a substantial number of MDRs and complaints reporting material health risks to patients, all of which when disclosed would adversely impact Intuitive's business; and (vi) Defendants failed to report, or timely report, complaints of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

125. On October 18, 2012, Defendants caused the Company to file its third quarter Form 10-Q for the period ending September 30, 2012 (the "3Q12 Form 10-Q"), which was signed by

defendant Mohr. The 3Q12 Form 10-Q also contained SOX Certifications, signed by defendants Guthart and Mohr, which were substantially similar to those set forth above. In the 3Q12 Form 10-Q, Defendants made the same representations set forth *supra* in paragraph 188 describing da Vinci as a "a new generation of surgery" which "combines the benefits of [MIS]" with those of open surgery.

126. In touting the benefits of "da Vinci Surgery," Defendants concealed that far from "combin[ing] the benefits of [MIS]" (including shorter recovery times and fewer complications) with those of open surgery, da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects present in da Vinci, resulting in (i) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (ii) the issuance of a substantial number of MDRs and complaints reporting material health risks to patients as a result of da Vinci, including six death-related reports in the three months between June 30, 2012 and September 30, 2012; and (iii) at least 12 personal injury and/or product liability lawsuits against Intuitive were filed between March 18, 2010 to September 30, 2012, five of which alleged injuries associated with Microcracks/insufficient insulation - Monopolar current.

127. The 3Q12 Form 10-Q also repeated, "[t]here have been no changes to the Risk Factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011." The risk factors in the 2011 Form 10-K included warnings concerning possible product defects and their potential impact, possible "performance problems in the future," and the "possibility that defects in the design or manufacture of our products might necessitate a product recall."

128. The 3Q12 Form 10-Q representations were materially false and misleading because they failed to disclose that (i) da Vinci posed a material health risk to patients; (ii) da Vinci already had known defects; (iii) Defendants had violated FDA regulations by failing to report to the FDA

corrective actions taken by Defendants to reduce health risks posed by da Vinci; (iv) Defendants had failed to report, or timely report, adverse events through the MDR mechanism, as required by 21 C.F.R. § 803.50; (v) Defendants had violated Current Good Manufacturing Practice (CGMP) requirements, as set forth in the Quality System regulation (21 C.F.R. § 820); and (vi) Defendants had already undertaken three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA in its Warning Letter. According to the FDA Warning Letter and Form 483, Intuitive had undertaken these recalls after receiving over 166 complaints and 87 MDRs since July 2009, the vast majority of which concerned the Tip Covers. The FDA Warning Letter further determined that Intuitive ignored design deficiencies in violation of CGMP even though it was aware of patient injuries in 2010 and 2011 due to the intraoperative cleaning of Monopolar Scissors.

129. In addition, the 3Q 2012 Form 10-Q, contained a section entitled "Risk Factors," stating that there had been "no changes to the Risk Factors discussed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011," filed on February 6, 2012. In the 2011 Form 10-K, Defendants represented that "the use of our products could result in product liability and negligence claims that could be expensive, divert management's attention and harm our business." The 2011 Form 10-K had further stated:

> Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of our products were to cause injury or death. There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall. Any weaknesses in training and services associated with our products may also be subject to product liability lawsuits. . . . .A product liability or negligence claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Product liability claims have been made against our company in the past. A product liability claim or any product recalls could also harm our reputation or result in a decline in revenues.

130. The 3Q 2012 Form 10-Q also represented that "[f]rom time to time, we may be involved in a variety of claims . . . relating to securities laws, product liability, patent infringement,

contract disputes and other matters relating to various claims that arise in the normal course of our business."

131. These statements were materially false and misleading because they failed to disclose that:

(a) as of October 18, 2012, at least five lawsuits filed against Intuitive alleged that patients had been harmed by Microcracks/insufficient insulation – Monopolar current; and

(b) it was highly likely that additional suits would be filed in the future because (i) da Vinci posed a material health risk to patients; (ii) Defendants had taken corrective actions to reduce health risks in October 2011, but hundreds of thousands of surgeries had been performed with da Vinci already before that date; (iii) Defendants had caused Intuitive to be in violation of CGMP, in part, due to missing critical design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (iv) there had been a substantial number of MDRs and complaints reporting material health risks to patients; and (vi) Defendants had failed to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

132. The 3Q 2012 Form 10-Q reiterated the financial results announced in the October 16th Press Release and October 16th Earnings Call. These financial results were materially false and misleading.

133. On January 22, 2013, Defendants caused the Company to file with the SEC a Form 8-K attaching a press release announcing Q4 2012 financial results (the "January 22nd Press Release"). Defendant Guthart stated in the release that the "results reflect expanding da Vinci Surgical System use across a broadening array of procedures and strong execution by our team." The release also reported, (i) revenue of $609 million for Q4 2012, up approximately 23% compared with $497 million in Q4 2011, driven by "continued adoption of da Vinci surgery procedures and higher da Vinci Surgical System sales;" and (ii) "da Vinci surgical procedures grew

approximately 25% in the fourth quarter of 2012 compared to the fourth quarter of 2011, driven primarily by U.S. gynecology and general surgery growth, and partially offset by a decline in U.S. prostatectomy procedures."

134. In the midst of changing Intuitive's previously deficient reporting process, but before the rise in MDRs contributed to heightened awareness of da Vinci's problems in the public markets, the Insider Selling Defendants capitalized on their insider knowledge by selling vast amounts of Intuitive stock. Collectively, the Insider Selling Defendants sold an extraordinary sum, exceeding $89 million between late October and early December of 2012. Individually, in late October, defendants Guthart and Mohr sold 4,500 and 7,300 shares, respectively, reaping proceeds of approximately $2.4 million and $3.9 million respectively. This was particularly striking in the case of defendant Guthart, who had refrained from selling since August 2008. Defendant Smith sold in late October and all throughout November, on no fewer than eight occasions, ***more than 125,000 shares*** of Intuitive common stock for ***almost $70 million***. Upon information and belief, most of defendant Smith's sales were not pursuant to a pre-arranged 10b5-1 trading plan.

135. During a January 22, 2013 conference call (the "January 22nd Earnings Call") discussing Q4 2012 results defendant Guthart also stated that:

(a) "[y]ear-over-year growth in procedures finished at 25%, led by continued uptake in gynecology and growing use of da Vinci in General Surgery"; and

(b) "Looking back at the full year 2012, our operating highlights are as follows. Worldwide procedures grew by approximately 25%. We sold 620 da Vinci Surgical Systems in the year, up from 534. Total revenue grew to $2.178 billion, up 24% over 2011. . . . Turning to operating highlights for the fourth quarter, procedures grew approximately 25% over the fourth quarter of last year. We sold 175 da Vinci surgical systems, up from 152 in the fourth quarter of 2011. Total revenue for the quarter was $609 million, up 23% from the fourth quarter of 2011."

136. Defendant Mohr reported during the call that fourth quarter 2012 systems revenue totaled "$265 million, and had increased 18% compared with $225 million for the fourth quarter of 2011."

137. Defendants' statements in the January 22nd Press Release and January 22nd Earnings Call were materially false and misleading because Defendants failed to disclose that da Vinci, which was solely responsible for the Company's sales and revenue growth, would be materially impacted by the following: (i) da Vinci posed a material health risk to patients; (ii) Defendants had violated FDA regulations by failing to properly report corrective actions it took to reduce health risks posed by da Vinci; (iii) Defendants had instituted three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (iv) Defendants had caused Intuitive to be in violation of CGMP, in part, due to critical missing design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (v) there had been a substantial number of MDRs and complaints reporting material health risks to patients, all of which when disclosed would adversely impact the Company's business; and (vi) Defendants had failed to report, or timely report, complaints of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

138. On February 4, 2013, Defendants caused the Company to file its Form 10-K for the year ending December 31, 2012 (the "2012 Form 10-K"). The 2012 Form 10-K was signed by signed by defendants Guthart, Mohr, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk and also contained SOX Certifications signed by defendants Guthart and Mohr, which were substantially similar to those set forth above. In the 2012 Form 10-K, Defendants repeated the representations calling the "da Vinci Surgical Systems ... a new generation of surgery" and touting it as "combin[ing] the benefits of minimally invasive surgery ("MIS") for patients with the ease of use, precision and dexterity of open surgery." Defendants further represented that "[o]ver the past two decades, MIS ha[d] reduced trauma to the patient by allowing selected surgeries to be

performed through small ports rather than large incisions, often resulting in shorter recovery times, fewer complications and reduced hospitalization costs."

139. In touting the benefits of the "da Vinci Surgical System," Defendants concealed that far from "extend[ing] the benefits of MIS" (including shorter recovery times and fewer complications), da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects, resulting in (i) Defendants instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (ii) issuance of 1,597 MDRs, including 32 death-related reports, being filed in 2012 related to da Vinci, reflecting a disproportionate 214 percent increase from 2011; (iii) at least 14 personal injury and/or product liability lawsuits filed against Intuitive between March 18, 2010 and December 31, 2012, half of which alleged injuries associated with Microcracks/insufficient insulation – Monopolar current; and (iv) the FDA commencing a safety probe in January 2013 in response to the increase in number of da Vinci-related MDR reports.

140. The 2012 Form 10-K repeated the statements from Intuitive's 2011 Form 10-K set forth above, warning against possible product defects and their potential impact, possible "performance problems in the future," and the "possibility that defects in the design or manufacture of our products might necessitate a product recall."

141. The 2012 Form 10-K representations were materially false and misleading because they failed to disclose that (i) da Vinci posed a material health risk to patients; (ii) da Vinci already had known defects; (iii) Defendants had violated FDA regulations by failing to report to the FDA corrective actions taken by Defendants to reduce health risks posed by da Vinci; and (iv) Defendants had already undertaken three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA in its Warning Letter. According to the FDA Warning Letter and Form 483, Intuitive had undertaken these recalls

after receiving over 166 complaints and 87 MDRs since July 2009, the vast majority of which concerned the Tip Covers. The FDA Warning Letter further determined that Intuitive ignored design deficiencies in violation of CGMP even though it was aware of patient injuries in 2010 and 2011 due to the intraoperative cleaning of Monopolar Scissors.

142. At the time the 2012 Form 10-K was filed, these statements were materially false and misleading because they failed to disclose that, according to the FDA Warning Letter issued by the FDA on July 16, 2013, Defendants had systematically violated FDA regulations by: (i) secretly issuing corrections starting in October 2011 related to defects without properly reporting those corrections to the FDA in violation of 21 C.F.R. § 806.10; and (ii) significantly deviating from the Current Good Manufacturing Practice (CGMP) requirements for devices, as set forth in the Quality System regulation (21 C.F.R. § 820). Defendants' statements were further materially false and misleading because they failed to disclose Defendants' failure to report, or timely report, reports of adverse events through the MDR mechanism, as required by 21 C.F.R. § 803.50.

143. In addition, the 2012 Form 10-K represented that:

(a) Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we face financial exposure to product liability claims if the use of our products were to cause injury or death. There is also the possibility that defects in the design or manufacture of our products might necessitate a product recall. Any weaknesses in training and services associated with our products may also be subject to product liability lawsuits. . . . If a patient is harmed during a da Vinci surgical procedure, even in the absence of any alleged system malfunction or defect, we can be exposed to negligence claims based on alleged inadequacies in our surgeon training, our training of our personnel, or in our proctoring programs. A negligence claim, regardless of its merit or eventual outcome, could result in significant legal defense costs. Negligence claims have been made against us in the past.

(b) "[f]rom time to time, we may be involved in a variety of claims, lawsuits, investigations and proceedings relating to securities laws, product liability, patent infringement, contract disputes and other matters relating to various claims that arise in the normal course of our business."

(c) With respect to product liability actions specifically, the Form 10-K stated "[w]e are aware of increasing efforts by plaintiff's attorneys to solicit da Vinci patients for product liability lawsuits against the Company. The Company cannot yet estimate the impact of these solicitations."

144. These statements were materially false and misleading because they failed to disclose that:

(a) as of February 4, 2013, at least eight product liability lawsuits alleged that patients had been harmed by Microcracks/insufficient insulation - Monopolar current; and

(b) it was highly likely that additional suits would be filed in the future because (i) da Vinci posed a material health risk to patients; (ii) Defendants had taken corrective actions to reduce health risks in October 2011, but hundreds of thousands of surgeries had been performed with da Vinci already before that date; (iii) Defendants had caused Intuitive to be in violation of CGMP, in part, due to critical missing design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (iv) there had been a substantial number of MDRs and complaints reporting material health risks to patients; and (v) Defendants had failed to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

145. The 2012 Form 10-K reiterated the financial results announced in the January 22nd Press Release and January 22nd Earnings Call. These financial results were materially false and misleading.

146. In addition to flagrantly failing to report deaths and other serious injuries to the FDA,

Defendants caused Intuitive to also misclassify the injuries that it actually reported to minimize their import. On March 13, 2013, the Defendants caused the Company to issue a press release (filed on March 14 with the SEC on Form 8-K) (the "March 13 Press Release"), admitting that until September 2012 the Company had been improperly classifying serious injuries as "other." After that date, Defendants caused Intuitive to elevate the same events to the category of "serious injury." Defendants had thus admitted that until September 2012 they had been underreporting "serious injuries" arising from da Vinci surgeries. The effect of the reclassification was to almost double the number of serious injuries in 2012 to 131.[9] Defendants have provided no sufficient explanation for their failure to properly report serious injuries and how serious injuries could possibly have been classified with the innocuous label of "other."

147. The March 13 Press Release further admitted that Intuitive (under Defendants' direction and on their watch) had not been reporting MDRs properly to the FDA. In a cryptic disclosure, defendants stated that in September 2012 the Company had "revised its MDR practices," which had then resulted in "increased reports." Defendants again did not explain the nature of the revision. Simply put, Defendants had caused Intuitive to withhold MDRs from the FDA in an effort to minimize the number and import of any negative adverse events.

148. The March 13 Press Release stated: "[i]n response to general inquiries regarding a recent rise in Medical Device Reports (MDR) filed by Intuitive Surgical, the company explained that the noted rise [did] not reflect a change in product performance but rather a change in MDR reporting practices."

149. Defendants further characterized the change in reporting practices as an

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[9] Suntrust Analyst Report, "ISRG-Thoughts on Updated Reporting Practices," dated March 14, 2013.

"administrative change in how MDRs previously reported as adverse events were subcategorized. This change has not increased the total number of adverse event reports. This will result in an increase in events in the 'serious injury' subcategory and a corresponding decrease in the 'other' subcategory. Total adverse event rates have remained low and in line with historical trends."

150. Defendants' statements were materially false and misleading because they failed to disclose that (i) in 2012 there had been a 214% increase in MDRs related to product performance compared to 2011, which exceeded "historical trends" and the increasing use of the da Vinci products; and (ii) that this increase in MDRs had caused the FDA to initiate a safety probe to find the root cause for the increase and evaluate product performance.

151. It has been alleged that Defendants' underreporting of MDRs is corroborated by a former Intuitive Regulatory Specialist, who worked at Intuitive from July through September 2012 in Sunnyvale, California (the "Regulatory Specialist"), and was responsible for complaint management and escalation of MDRs. It has been alleged that the Regulatory Specialist was aware of complaints and reports of additional burns related to the Tip Covers, even after Intuitive modified the Tip Cover's design.

152. It has been alleged that, according to this former Regulatory Specialist (and as also reported by Defendants in the Company's March 2013 Press Release), Intuitive changed its reporting criteria in September 2012 when the Defendants began reporting issues that had previously not been reported. It has been alleged that the Regulatory Specialist said that the change occurred after Richard Reeves, the Director of Regulatory Affairs, met with representatives from the local office of the FDA in late August or early September. It has been alleged that the Regulatory Specialist's understanding is that Intuitive changed its reporting criteria because of increased scrutiny by the FDA on robotic surgical platforms.

153. During Intuitive's April 18, 2013 earnings conference call (the "April 18th Earnings

Call"), defendant Guthart stated:

> As you know, we are in the midst of a concerted effort by critics of robotic surgery to challenge the benefit it brings to patients…[w]e are confident that those who invest their time in a serious review of the clinical literature on da Vinci will find ample evidence of the benefit it brings to patients, surgeons, hospitals and the medical community at large.

154. Defendant Guthart further stated that "da Vinci surgery has proven safety, efficacy, economic and ergonomic benefits when compared to the open surgical procedures it is replacing."

155. Defendant Guthart's statements were materially false and misleading because they denied the validity of the safety issues even though defendant Guthart knew and failed to disclose that, (i) da Vinci posed a material health risk to patients; (ii) da Vinci already had known defects; (iii) Intuitive had violated FDA regulations by failing to report to the FDA corrective actions taken by Defendants to reduce health risks posed by da Vinci; (iv) Defendants had already undertaken three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA in its Warning Letter; (v) the issuance of a substantial number of MDRs and complaints reporting material health risks to patients as a result of da Vinci in the three months between January 1, 2013 and March 31, 2013; (vi) Defendants had failed to report, or timely report, adverse events through the MDR mechanism, as required by 21 C.F.R. § 803.50; (vii) Defendants had violated Current Good Manufacturing Practice (CGMP) requirements, as set forth in the Quality System regulation (21 C.F.R. § 820); (viii) at least 16 personal injury and/or product liability lawsuits had been filed against Intuitive between March 18, 2010 and April 18, 2013, nine of which alleged injuries associated with Microcracks/insufficient insulation – Monopolar current; (ix) the FDA had commenced a safety probe in January 2013 in response to the increase in number of da Vinci-related MDR reports; and (x) the FDA had commenced an inspection of Intuitive's facilities on April 1, 2013 during which numerous safety related violations were found.

156. In addition, in the April 18th press release (the April 18th Press Release"), defendant Guthart commented: "We are pleased with our first quarter revenue and earnings growth. Despite a concerted effort by vocal critics of robotic surgery, support remains strong among patients, surgeons and hospitals . . . . da Vinci Surgery has clinically proven benefits in offering a minimally invasive option to a broader group of patients than traditional technologies." The release also reported that (i) revenue of $611 million for Q1 2013, up 23% compared with $495 million in Q1 2012, was "driven by continued growth of da Vinci surgery procedures and higher da Vinci Surgical System sales;" and (ii) "da Vinci surgical procedures grew approximately 18% in the first quarter of 2013 compared to the first quarter of 2012, driven primarily by growth in general surgery, U.S. gynecology and international urology procedures, partially offset by a decline in U.S. prostatectomy procedures."

157. During the April 18, 2013 Earnings Call discussing Q1 2013 results, defendant Guthart also stated that:

(a) "we experienced strong growth in general surgery, slower growth in gynecology and a return to stability in urology. This resulted in an 18% procedure growth over 2012. The first quarter of 2013 had one fewer surgery day than 2012. Taking this into account, normalized procedure growth improves to approximately 20%"; and

(b) "[t]otal revenue was $611 million, up 23% over last year."

158. Also during the call, defendant Mohr reported that first quarter 2013 systems revenue totaled $256 million, an increase of 24% compared with $207 million for the first quarter of 2012.

159. Defendants' statements in the April 18th Press Release and April 18th Earnings Call were materially false and misleading because Defendants failed to disclose that da Vinci, which was solely responsible for the Company's sales and revenue growth, would be materially impacted by the following: (i) da Vinci posed a material health risk to patients; (ii) Defendants had violated FDA

regulations by failing to properly report corrective actions it took to reduce health risks posed by da Vinci; (iii) Defendants had instituted three secret recalls in October 2011 to reduce risks to health posed by da Vinci; (iv) Defendants had caused Intuitive to be in violation of CGMP, in part, due to critical missing design inputs necessary to address the intraoperative cleaning of Monopolar Scissors; (v) there had been a substantial number of MDRs and complaints reporting material health risks to patients, all of which when disclosed would adversely impact the Company's business; and (vi) Defendants had failed to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50).

160. On April 19, 2013, Defendants caused the Company to file its first quarter 2013 form 10-Q for the period ending March 31, 2013 (the "1Q13 Form 10-Q"), which was signed by defendant Mohr. The 3Q12 Form 10-Q also contained SOX Certifications, signed by defendants Guthart and Mohr, which were substantially similar to those set forth above. In the 1Q13 Form 10-Q, Defendants (a) repeated the representations in Intuitive's 3Q12 Form 10-Q, describing da Vinci as a "a new generation of surgery" and touting its advantages of combining the benefits of both open surgery and MIS; and (b) reported that "during the first quarter of 2013, there have been articles published and papers written questioning patient safety and efficacy associated with da Vinci Surgery…We believe that da Vinci Surgery continues to be a safe and effective surgical method…"

161. The 1Q 2013 Form 10-Q representations were materially false and misleading because they failed to disclose that, (i) da Vinci posed a material health risk to patients; (ii) da Vinci already had known defects; (iii) Intuitive had violated FDA regulations by failing to report to the FDA corrective actions taken by Intuitive to reduce health risks posed by da Vinci; (iv) Defendants had already undertaken three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA in its Warning Letter; (v)

Defendants had failed to report, or timely report, adverse events through the MDR mechanism, as required by 21 C.F.R. § 803.50; (vi) Intuitive had violated Current Good Manufacturing Practice (CGMP) requirements, as set forth in the Quality System regulation (21 C.F.R. § 820); (vii) the issuance of a substantial number of MDRs and complaints reporting material health risks to patients as a result of da Vinci, including six death-related reports in the three months between January 1, 2013 and March 31, 2013; (viii) at least 16 personal injury and/or product liability lawsuits had been filed against Intuitive between March 18, 2010 and April 18, 2013, nine of which alleged injuries associated with Microcracks/insufficient insulation – Monopolar current; (ix) the FDA had commenced a safety probe in January 2013 in response to the increase in number of da Vincirelated MDR reports; and (x) the FDA had commenced an inspection of Intuitive's facilities on April 1, 2013 during which numerous safety related violations were found.

162. In addition, the Form 10-Q reiterated the financial results announced in the April 18th Press Release and April 18th Earnings Call. These financial results were materially false and misleading.

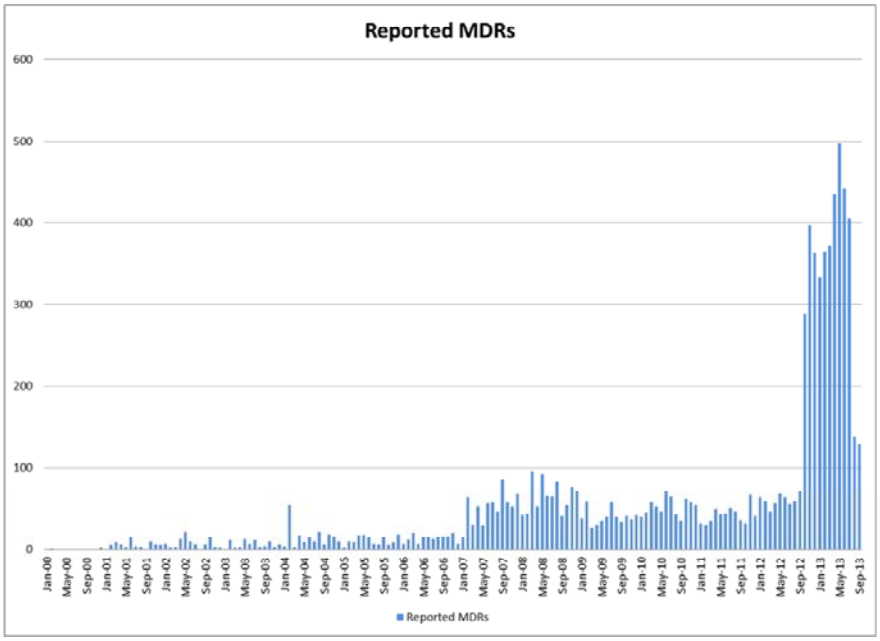
B. The Number of Medical Device Reports Increased Dramatically After The Change In Reporting In September 2012 Showing That Intuitive Had Systematically Concealed Adverse Events

163. Once Defendants caused Intuitive to begin accurately classifying and reporting MDRs in September 2012, the number of MDRs in the MAUDE database skyrocketed.[10] For the prior 12 years, from 2000-2012, there had been 5,333 da Vinci-related MDRs filed. This number

[10] It has been alleged that to evaluate the rise in defects and injuries related to da Vinci, the plaintiffs in the Securities Action analyzed the MAUDE database that is publicly available from the FDA website (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). This analysis was only possible after Defendants caused Intuitive to start complying with FDA regulations and stopped underreporting and misclassifying MDRs, as reported by Defendants in March 2013.

grew dramatically to over 8,450 MDRs, after a staggering 3,117 da Vinci-related MDRs were filed with the FDA in the nine months from January 1 to September 30, 2013 alone. This represents an astounding 40 percent increase in 2013 compared to all prior years cumulatively. In other words, Defendants had caused Intuitive to suppress nearly half of all MDRs.

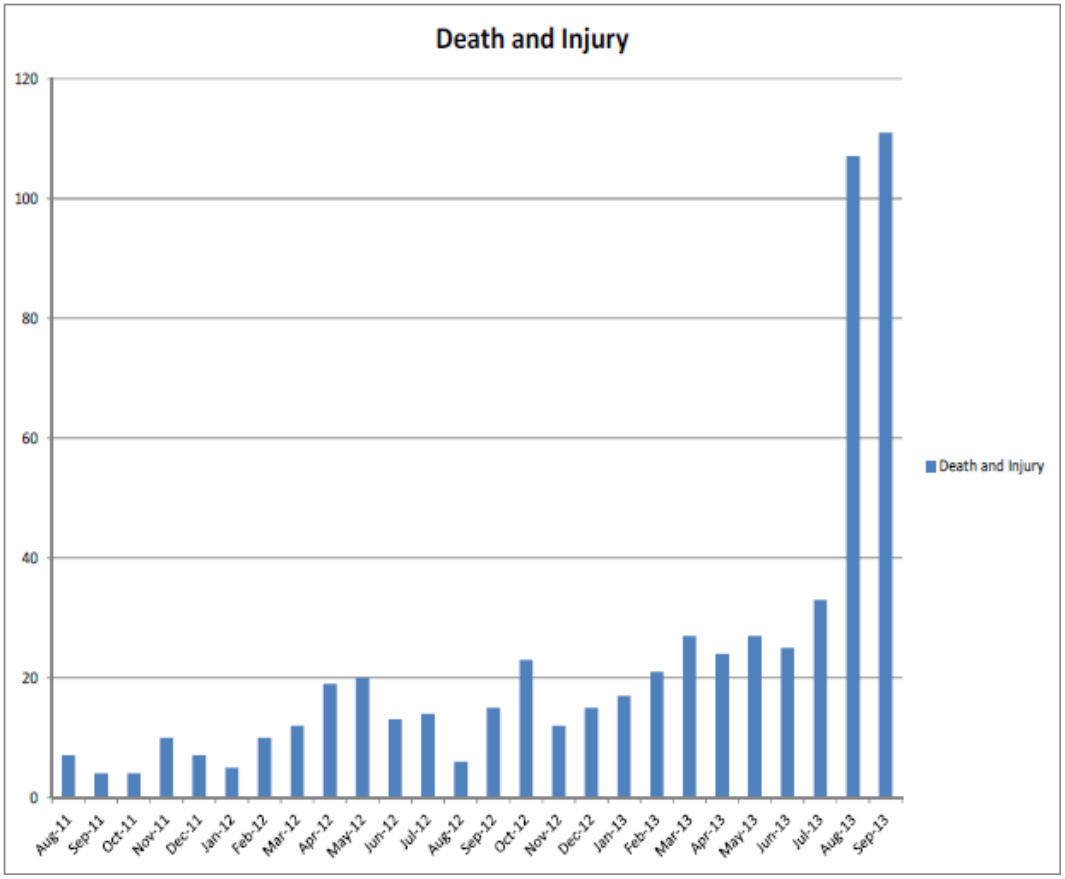
164. The extent of Defendants' scheme is also evident in the monthly reporting figures. With an average rate of over 400 MDRs a month filed during the first seven months of 2013, this is more than five times higher than any prior period since da Vinci was introduced in 2000. The chart below, showing the number of MDRs submitted to the FDA on a monthly basis from January of 2000 through September 2013, highlights the stunning increase after the meeting with the FDA in September 2012 left Intuitive no choice but to begin accurate reporting:



165. Further, not only did the total number of MDRs grow on a large scale, so did those reporting "injuries" and "death." In August 2013 the number of "injury" and "death" type events swelled to more than 100 – more than triple the rate of any other month. These 100-plus reports are apparently due to a mass posting of over 70 "injury" or "death" events which are annotated "as part of a legal mediation effort" in the Company's inserted notes. Altogether there are over 20 such

"legal complaint" reports, all "injury" or "death" event types, filed in the last four months, most of which show a time lag between event date and date reported of six months to three or more years. In other words, the adverse events had taken place years before and not reported by Defendants to the FDA.

166. The chart below visually demonstrates the massive increase in MAUDE "death" and "injury" reports:



167. Equally telling from this chart is the obvious increase in MDRs beginning in November 2012 and the rapid acceleration thereafter. While "death" and "injury" reports between August 2011 and August 2012 averaged about 10 per month, from September 2012 through September 2013 they averaged 35, a more than three-fold increase as they continued to rise and exceed 100 by August 2013. The increase reflects "injuries" and "deaths" that had been concealed

by Defendants and were only reported much later. Defendants thus concealed hundreds of "injuries" and "deaths."

C. Defendants Caused Intuitive to Use Aggressive Sales Tactics And Marketing Strategies Disregarding Patients' Safety

168. While Defendants fiercely sought to conceal and minimize the disclosures regarding the extent and severity of patients' injuries caused by da Vinci, they also caused the Company to engage in extremely aggressive marketing practices to sell its only product. These marketing practices reflect that Defendants had little regard for the safety of patients; Defendants and the Company's sales personnel simply wanted to make their numbers. In order to do this, Intuitive's sales force employed all kinds of stratagems to increase the number of procedures using da Vinci and ultimately the number of sales of da Vinci systems.

169. For example, according to an article published on March 25, 2013 by *The New York Times* ("*NYT*"), Intuitive's sales force consistently sought to circumvent or minimize surgeon training requirements designed to ensure patients' safety in order to increase the number of procedures:[11]

> In an [internal Intuitive] e-mail dated May 31, 2011, a Western regional sales manager for Intuitive noted that area surgeons had used robotic equipment only five times, although the company's goal was to see 36 robotic operations performed by the end of June. He urged sales staff to persuade surgeons to switch upcoming cases to robotic ones.
>
> "Don't let proctoring or credentialing" — shorthand for supervised surgery and hospital certification — "get in our way," the e-mail said.

170. The effort to increase procedures by disregarding surgeon training also consisted of applying direct pressure on hospitals:

> In December 2009, a sales representative urged a hospital in Billings, Mont., to ease up on its credentialing requirement, saying in an e-mail that requiring surgeons to do

[11] *Salesmen In the Surgical Suite*, Roni Caryn Rabin.

> five supervised operations using the robot before going solo was "on the high side" and could have "unintended consequences." Hospital officials replied, saying, "We will review and most likely will decrease the 5 down to 3."

171. In another email cited in the article, a clinical sales director instructed the sales team to "'scrub' doctors' schedules and get procedures moved up by a few days in order to make [Intuitive's] quarterly goal." And in a third email referenced by the *NYT*, a clinical sales director told the sales team to "[b]e prepared to challenge each trained surgeon every time you see a lap[aroscopic] or open case. Be unsatisfied with the thought of ending a day without a converted case," meaning pressuring a surgeon to use da Vinci instead of operating laparoscopically or with an open incision. In fact, the sales force was so entrenched in the hospital decision-making process and daily routines that Intuitive sales representatives were even present inside the operating rooms during surgery, offering advice to newly trained surgeons if they were having technical difficulties with the robot.

172. Another aggressive tactic employed by Defendants in marketing da Vinci was the use of seemingly independent medical professors who promoted the device, even in the face of growing safety concerns, without disclosing the financial incentives received from the Company. According to an article published on September 20, 2013 in the *Orange County Register*, "UCI Doctors Downplayed Risks Of Surgical Robot," at least two seemingly independent professors touted da Vinci while reaping undisclosed financial rewards. Specifically, professors Ralph Clayman and Thomas Ahlering provided Intuitive with so-called independent opinions that da Vinci was safe. But undisclosed was the fact that Defendants had caused Intuitive to pay professor Ahlering, or his foundation, at least $107,000 since 2002, and that Defendants had caused Intuitive to also be a top financial supporter of an academic society co-founded by professor Clayman, which paid him $30,000 per year. The article further reported that Defendants had also caused Intuitive to give University of California Irvine, the school where Clayman was dean, nearly $1.5 million in

grants and reimbursements. Intuitive was thus able to promote da Vinci as safer than it was, through the use of professors who were viewed as disinterested, but were decidedly not.

173. These sales and marketing techniques were all the more successful because Defendants omitted to tell these doctors and patients (or the FDA) of the growing health risks associated with da Vinci procedures and defects in the da Vinci instruments and accessories.

THE TRUTH EMERGES

A. The FDA Takes Strong Regulatory Action

1. The 2013 FDA Probe: In January 2013 The FDA Began To Uncover Significant da Vinci-Related Defects And FDA Violations

174. On the heels of the September 2012 reclassification of serious injuries, the FDA noted an increase in the number of reports of adverse events. Given that Defendants had caused the Company to previously "down-code" the adverse reports without providing any justification, the FDA this time leapfrogged Intuitive's role in the reporting chain of custody and went directly to the source, the physicians. In a letter-survey to physicians, the FDA asked them to provide information about adverse events related to da Vinci directly to the FDA, not Intuitive. The letter further indicated that the survey would not be limited to a question and answer form, but that agency officials would speak with surgeons for up to an hour.

175. "What the FDA [was] trying to determine with the survey [was] whether adverse event reports sent to the agency [were] **'a true reflection of problems'** with the robots, or the result of other issues, Synim Rivers, an agency spokeswoman" said in an e-mail reported by Bloomberg.[12] According to *Bloomberg*, Ms. Rivers added "[i]t is difficult to know why the reports have increased." In fact, *Bloomberg* broke the news of the FDA probe on February 28, 2013, five

[12] Intuitive Surgical Robots Probed by U.S. in Surgeon Survey (2), February 28, 2013, released at 18:14.

minutes before the close of the stock market, causing Intuitive's stock price to fall 11 percent by the close to $509.89.

176. Commenting on the news of the FDA probe, Michael Matson, an analyst with Mizuho Securities in New York, said that a rise in adverse events was a concern because "patients would get scared." "Part of what's driven this market is people seeking out robotic surgery – hospitals market it and the patients seem to think it's better." Matson then concluded that Intuitive's stock was likely going to remain under pressure until the Company could prove that the safety worries were not significant. *Id.*

177. A further stock drop on March 5, 2013 resulted from related news being reported by *Bloomberg* on the rise in incident reports, deaths related to da Vinci complications, and allegations of product liability suits pending against the Company as related to complications during robotic surgery.

2. First Quarter 2013 Results Were Impacted By The FDA Probe And Reclassification Of Serious Injuries

178. News of the FDA probe and the increase in serious injuries had an impact in the number of da Vinci procedures in the first quarter ending March 31, 2013. Analysts surmised that this could happen. A prior analyst report issued by Canaccord Genuity, dated March 18, 2013, revisited the negative headlines associated with Intuitive in the prior months, and concluded that,

> **the cadence of negative news** over the past several months has **increased the risk to ISRG's financial performance**….the pullback in ISRG's share price is warranted given the real possibility, in our mind, that system sales and **procedure growth could be impacted** should hospital administrators delay purchasing the robotic system in light of the aforementioned studies and negative press.

179. When Defendants caused Intuitive to announce first quarter results on April 18, 2013, "the cadence of negative news" had begun to reduce the number of surgeries using da Vinci. According to a JP Morgan report dated April 19, 2013, "results were decidedly mixed … [with] the all-important procedure growth number falling short." JP Morgan also highlighted the importance

of procedure growth, stating, "[w]e have consistently argued that procedure growth is the key metric for investors, and are not changing our tune." (emphasis in original). Other analysts reached the same conclusion. A report by Leerink Swann that same day was titled, "Solid 1Q Beat Overshadowed by Light Procedure Growth."

180. Wall Street thus understood that, although Intuitive had performed well in terms of revenues and profits in the first quarter of 2013, the future did not portend well given that the use of da Vinci surgeries was stalling. Indeed, before the end of the first quarter, Defendants had caused Intuitive to forecast procedure growth for all of 2013 to range between 20 and 23 percent. Procedures during the first quarter had increased only by 18 percent.[13] Investors agreed with the analysts' dire assessment, causing Intuitive's stock price to drop $8.62 to $484.75 after the announcement.

181. Defendant Guthart sought to minimize the negative news and the numerous questions from analysts about the impact of the FDA probe and issues with da Vinci at the earnings conference call that quarter held on April 18, 2013. Guthart attempted to discredit the negative reports by raising the specter of a conspiracy: "we are in the midst of a concerted effort by critics of robotic surgery to challenge the benefit it brings to patients." Guthart then effectively denied the validity of safety concerns with da Vinci, further concealing the action the Company had taken to hide the extent of the actual problems. Guthart stated, "[w]e are confident that those who invest their time in a serious review of the clinical literature on da Vinci will find ample evidence of the benefit it brings to patients, surgeons, hospitals and the medical community at large."

182. Despite defendant Guthart's efforts to preempt the analysts' concerns, the first

[13] Total procedures in 2012 had reached approximately 450,000 compared to about 360,000 and 278,000 in 2011 and 2010 respectively. That represented procedure growth of almost 30% in 2011 and 25% in 2012.

question on the April 18th earnings call related to the impact of the da Vinci safety issues on the number of procedures. Evan Lodesen from JP Morgan asked Guthart, "Can you disaggregate the slowdown in benign [hysterectomies] between the seasonal effects that you mentioned such as deductibles and then also the more coordinated efforts that you talked with regards to the robot, specifically?" Guthart admitted that the negative news had impacted the number of procedures, although he was not able to quantify it: "negative press has some hard-to-measure impact on benign hysterectomy, although it doesn't appear to be large. It's also probably not zero."

183. Other analysts on the call made similar inquiries. David Roman from Goldman Sachs asked: "any sort of impact you have had from the recent noise in the marketplace, what is your plan to start to stem that and then how long do you think it might take before we start to see some positive returns from those efforts?" Guthart responded that it was "hard" to assess.

184. Amit Hazan, from SunTrust Robinson Humphrey, then asked directly about the FDA probe: "[d]o you know anything about the report [referring to the FDA survey] that might be coming out with what you might be anticipating?" Guthart said, "we have no – nothing to share on that front," stopping himself short of apparently saying "we have no information."

3. The Form 483 Issued In May 2013 Documented Numerous Violations Including The Secret Recall Of Tip Covers In 2011

185. Between April 1 and May 30, 2013, the FDA inspected Intuitive's headquarters in Sunnyvale, California. The inspection was conducted under the supervision of FDA investigator, Mary R. Hole ("Hole"). At the end of the inspection, Hole issued a Form 483 addressed specifically to Defendant Guthart. An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has **observed any conditions that in their judgment may constitute violations of the [FDCA]** and related Acts....The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an

inspection, the FDA Form 483 is presented and **discussed with the company's senior management**.[14]

186. The FDA's Form 483 issued to defendant Guthart on May 30, 2013, reported four observations ("Observation"). Each of these observations detailed a deficiency in Intuitive's FDA reporting practices, and Observation Four further detailed the Company's failure to properly address a design failure related to the Monopolar Scissors.

187. **Observation One** documented four instances in which Intuitive had effectively conducted a secret recall, or in the regulatory language of the FDA, initiated a "correction or removal, conducted to reduce a risk to health posed by a device, [and] [had] not reported [it] in writing to the FDA." The first instance was described as follows:

(i) On 10/10/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with suggestions and recommendations for the proper use of instruments with **tip covers** for the correct generators that should be used with monopolar instruments. This action was not reported to the San Francisco District Recall Coordinator.

188. This recall of the Tip Covers by Intuitive had been a direct response to "**complaints and MDRs for arcing through damaged tip covers that caused patient injury.**" The Form 483 further observed that Intuitive's recall had been in response to 134 complaints, of which 82 resulted in MDRs related to Tip Cover issues.

189. **Observation One** included three additional instances in which Intuitive had effectively conducted a secret recall:

(ii) On 10/13/2011, Intuitive Surgical, Inc. sent out a letter notifying da Vinci clients that the da Vinci surgical systems are not cleared for thyroidectomy indication. This **action was not reported** to the San Francisco Recall Coordinator. The thyroidectomy indication was promoted by Intuitive Surgical, Inc….Between July 2009 and October 2011, Intuitive Surgical received 13 complaints and filed 5 MDRs

[14] *See* http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm; http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm.

related to thyroidectomies performed with the da Vinci system.

(iii) On 10/17/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with information for inspecting instrument cannulas, proper flushing instruments, and the proper transportation of the da Vinci between buildings. This **action was not reported** to the San Francisco Recall Coordinator….some of these issues have been previously identified as root causes in other complaints that gave rise to MDRs (for example, damage to the integrity of a tip cover due to defective cannulas was identified as one of the root causes for arcing that resulted in patient injuries). As such these issues represent a risk to the health of patients.

(iv) On 01/24/2013, Intuitive Surgical, Inc. sent out a letter and [a new User Manual Addendum for Transoral Surgery,] (TORS)….the new version [of the manual] warns that da Vinci TORS surgery is not indicated for pediatric patients, therefore the vagueness in the previous version [of the manual] represented a health risk to pediatric patients. (See Ex. B at 1-2, attached hereto).

190. **Observation Two** documented an instance in which Intuitive had misleadingly represented to the FDA its "corrective actions" as voluntary, while concealing that they had been the result of adverse event reports. In October 2011, Defendants caused Intuitive to withdraw the recommendation that da Vinci be used to conduct thyroidectomies without informing the FDA. Once the FDA began the April-May 2013 inspection, however, Defendants quickly sought to cover its tracks by reporting the withdrawal of the indication on April 11, 2013. But this belated report, more than 18 months after the fact and prompted by the on-site inspection, was also misleading. The April 2013 report sought to portray the withdrawal as *sua sponte* while concealing that the withdrawal had occurred only after receipt of at least five MDRs and over a dozen complaints.

> Specifically, Intuitive Surgical, Inc. **failed to report** that there were 5 MDRs associated with the field action taken on 10/13/2011 (Thyroidectomy indication withdrawal). The 806 report … that was supplied to the San Francisco District Coordinator on 4/11/2013 indicated 0 MDRs….During my inspection of Intuitive Surgical, Inc. 5 MDRs were represented as related to this correction.

191. **Observation Three** documented that Intuitive had concealed the initial decision to market da Vinci for thyroidectomies. Intuitive sent a "letter to file" instead of submitting a new premarket notification [510(k)], as required by 21 CFR 807.81(a)(3)(ii) for a major change or modification in the intended use of the device. Defendants profited from uncleared da Vinci

thyroidectomies for more than two years, between July 2009 and October 2011.

> Specifically, Intuitive Surgical, Inc. **did not document** the decision to add a thyroidectomy indication to the da Vinci system general laparoscopy clearance 510(k) No. K990144 through Letter to File rather than through the submission of a new 510(k) application.

192. **Observation Four** documented that Intuitive concealed an additional health risk created by the Monopolar Scissors. "Intuitive . . . ha[d] received complaints of arcing of energized surgical instruments as a result of surgeons cleaning off instruments [inside the patient's body] by scraping them across other surgical instruments. In the case of … the Monopolar [] Scissors … the scraping led to tears or holes in protective tip covers that led to arcing that in turn led to injuries to patients." This knowledge and awareness of the surgeons' need to clean the instruments inside the patient's body created a duty to design a safe cleaning process, which Intuitive ignored.

4. Second Quarter 2013 Results Reflected The Full Blown Financial Impact Of The FDA Probe And da Vinci's Safety Concerns

193. On July 8, 2013, Defendants caused the Company to issue a press release pre-announcing second quarter results. While Defendants had minimized the impact of da Vinci's safety concerns in the first quarter, they could no longer do so in the second quarter as the wheels came unhinged. The financial results were dismal and the reported number of procedures using da Vinci continued to deteriorate despite prior statements that the first quarter slow down had been temporary.

194. Revenues from da Vinci sales had declined six percent to $216 million in the second quarter of 2013, compared to $229 million in the same quarter in 2012. Intuitive had sold only 143 systems compared with 150 system in the second quarter of 2012, and 164 systems in the first quarter of 2013. And the number of procedures again grew only by 18 percent, so that, after six months, Intuitive's projected growth of 20 to 23 percent was no longer feasible.

195. The analyst reports reflected surprise at the unexpected nature and magnitude of the

decline. JP Morgan's report of July 8 called it "shocking": "The severity of the top line [revenue] shortfall, with the company posting revenues of $575M vs. consensus of $630 million [$622M JP Morgan] was shocking, and raises more questions than answers."

196. Analysts also remained skeptical that the severe decline was due to the excuse provided by Intuitive. Defendants claimed that the negative results were due to economic factors and hospitals cutting capital expenditures, such as the purchase of da Vinci systems. Morgan Stanley's July 17, 2013 report evidences skepticism: "We are less convinced a material change in the US CapEx [capital expenditure] environment explains the system shortfall in the quarter. Our Q1 and Q2 surveys showed a declining interest in robotics and hesitance to purchase a da Vinci despite a stable broader CapEx environment." Put simply, hospitals were not reducing expenditures. They were just not buying da Vinci systems, and one of the reasons was the "safety of robotic surgery," as Morgan Stanley explained in a subsection entitled, "A Review of Recent Pressures on da Vinci Procedures."

197. Canaccord's report dated July 9, 2013 expressed similar views: second quarter "results usurped our most bearish scenario; represented ISRG's worst system performance (-6% [year over year]) since the height of the financial crisis in [the third quarter of 2009]; and most notably, exhibited a significant deviation from historic growth trends – ISRG had reported system sales growth >15% for 9 consecutive quarters."

198. Canaccord also no longer viewed the negative results as cyclical or due to external factors, but systemic. "What's more, the factors cited by ISRG for the systems miss strike us as more systemic than isolated, thus could take longer to resolve, in our estimation." Canaccord then noted that in the second quarter press release Intuitive had blamed "economic pressures on hospitals which led to some deferred system purchases." Like Morgan Stanley, Canaccord remained skeptical. "This [the claim that hospitals had cut back] comes just three months after the company

reported Q1/13 system sales that were quite strong (+24% Y/Y), making the magnitude and speed with which this negative deviation from historical placement growth trends unprecedented in the company's history….We expect management to provide greater clarity on the factors impacting sales during the Q2 conference call on July 18, but for now we are left with many more questions than answers."

199. On this news, Intuitive's stock price dropped $80.78 per share, from $500.08 per share to $419.30 per share. *Bloomberg* reported that the Company's stock price "**fell the most since 2008** after reporting preliminary results that missed analysts' estimates as sales slowed for its surgical robots, which have faced **safety** and cost-efficiency questions."[15]

B. The FDA Warning Letter

1. On July 16, 2013 The FDA Issued A Warning Letter To Intuitive

200. Intuitive's Form 483 escalated into a Warning Letter in record time, between the end of the inspection on May 30 and July 16, when the FDA issued it. The FDA Warning Letter was addressed directly to Defendant Guthart.

201. Pursuant to the FDA's Regulatory Procedures Manual ("RPM"), **"Warning Letters are issued only for violations of regulatory significance.** Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected. A Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the FDCA." RPM § 4-1-1. Accordingly, Warning Letters establish that a violation of the FDCA has occurred. Importantly, "**[r]esponsible officials in positions of authority** in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices,

[15] Intuitive Surgical Declines on Falling da Vinci Robot's Drop in Sales (2) issued July 9, 2013 at 4:36 p.m.

processes, or other activities comply with the law. Under the law, such individuals **are presumed to be fully aware of their responsibilities**." *Id.*

202. The Agency issued the FDA Warning Letter after it received Intuitive's response on June 7, 2013 to the Form 483. The FDA found that the June 7 response was "incomplete and inadequate," and reached significant findings and conclusions.

203. First, the FDA Warning Letter concluded that the Tip Cover Accessory and Cannula 8mm Regular were "misbranded devices" under § 502(t)(2) of the FDCA, 21 U.S.C. 352(t)(2). Intuitive had "failed or **refused to furnish** material or information respecting the device." This referred to Intuitive's failure to notify the FDA of the changes to the Tip Covers and Cannulas set forth in Observation One of Form 483.

204. Second, and most importantly, the FDA determined that the four unreported corrections in Observation One of the Form 483 in which Intuitive had concealed changes to the Tip Covers and other procedures from the FDA constituted "Class II recall[s]." In each of the four instances the FDA Warning Letter stated: "Your report of this recall on April 19, 2013 has been classified by [the] FDA as a Class II recall." Accordingly, the FDA had determined that Intuitive had carried out four secret recalls, which the Defendants cause the Company to conceal during the Relevant Period, including recalling the Tip Covers.

205. The FDA Warning Letter further explained that Intuitive's belated excuse for not reporting the recalls was unacceptable. Defendants caused Intuitive to claim that it had changed an internal standard operating procedure so that "corrections, removals and labeling reiterations" (as Intuitive carried out here with respect to the Tip Covers) would be reported to the FDA local district director "or **3rd party expert**." This 3rd party expert option was nothing but a subterfuge. According to the FDA Warning Letter, such an option made it impossible for the FDA to evaluate the information to be provided to the FDA because that option allowed for no information at all to

be reported and did not explain Intuitive's basis for choosing between informing the FDA and the supposedly "3rd party expert."

206. Third, regarding Intuitive's failure to report these four corrections and removals, the FDA Warning Letter added, "**[t]he FDA has previously informed you of your firm's correction and removal violations** in an untitled letter dated February 19, 2008, and FDA 483 Inspectional Observations issued on December 20, 2002." In saying this, the FDA confirmed that failing to report corrections and removals was an ongoing, unsolved issue with Intuitive.

207. Fourth, the FDA Warning Letter found that Intuitive's devices were adulterated under § 501(h) of the FDCA, 21 U.S.C. § 351(h), because Intuitive had failed to fully implement the Quality System regulation regarding Design Control, as required by 21 C.F.R. § 820.30. Specifically, Intuitive knew "of patient injuries" concerning the Monopolar Scissors that required changes to the design of the Tip Covers and Cannulas but completely ignored those injuries and did nothing. The FDA Warning Letter added, "you informed our investigator that you are **aware of patient injuries** associated with intraoperative cleaning of energized instruments such as Monopolar Curved Scissors and Fenestrated Bipolar Scissors evidenced by at least [redacted] complaints and 82 MDRs during calendar years 2010 and 2011, and 15% of the MDRs reviewed by our investigator. You also informed our investigator that you are aware that cleaning instruments inside patients during surgery is a common practice and have included a label warning in the Instructions-for-Use (IFU) against the practice. **When our investigator asked you to provide the design input documentation and design resolution of this known user need you failed to provide the requested documentation**."

208. Defendants failed to provide the "design input documentation" and "design resolution" to the FDA because they had not even attempted to fix the actual design defect and had limited the Company to merely adding a label warning in the IFU. This "fix" shifted the burden for

preventing device related injuries to Intuitive's customers (*i.e.*, surgeons), instead of providing an adequately designed product that would not fail. It depended on the surgeon reading the changes and adequately modifying their behavior while the problematic devices continued to be distributed. Intuitive stated that they had adequately considered the cleaning requirement and the risks without going through the design control process. However, failing to properly determine the root cause of the problem by not following the design control process resulted in continued failure of the device with resulting injuries. The FDA concluded that this was "inadequate."

209. The term inadequate does not sufficiently describe the number and importance of FDA design control regulations that Defendants caused Intuitive to violate. Regulations over the design process required Intuitive to institute procedures "to ensure that the design requirements relating to a device are appropriate and address the **intended use of the device, including the needs of the user and patient**." 21 C.F.R. § 820.30(c). In this case, surgeons needed to clean the accumulated debris off of the Tip Covers during surgery without removing them from the patient. This recognized need is referred to in the regulations as "design input." The FDA Warning Letter concluded that Intuitive had never even attempted to address the problem, having never documented the design input.

210. Failing to even document the design input, Defendants caused Intuitive to never continue with the subsequent requisite design process and was thus unable to show the FDA the appropriate "design resolution" documentation. Under FDA regulations, had Intuitive identified and documented the design input, it would then have had to translate it into a "design output," 21 C.F.R. § 820.30(d). If the "user need" consisted of cleaning the Monopolar Scissors intraoperatively, as in this instance, then the design output required Intuitive to institute a procedure or a redesign of the equipment to clean intraoperatively without damaging the protective covering in order to prevent arcing.

211. After implementing a design output, Intuitive was required to document the "design verification," whereby Intuitive would have had to confirm that the design output met the design input requirements. 21 C.F.R. § 820.30(f). In this instance, if the design input constituted the surgeons' need to clean the Tip Covers, then Intuitive was required to design a fix to the problem that allowed for cleaning the Tip Covers without causing arcing – the design output. And after verifying the design, Intuitive was required to validate that the Tip Covers worked, *i.e.*, validate that the Tip Covers "conformed to defined user needs and intended uses," or intraoperative cleaning. 21 C.F.R. § 820.30(g) ("design validation").

212. Defendants ignored all of these design regulations rendering the Tip Cover Accessory and Cannula 8mm Regular "adulterated devices." The FDA Warning Letter admonished that the "**Tip Cover Accessory and Cannula 8mm Regular are adulterated devices** under section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements for devices which are set forth in the Quality System regulation," 21 C.F.R. § 820.

213. The FDA Warning Letter concluded with a stern admonition that the issues identified were not an all-inclusive list. "Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facilities." The letter further warned that the issues identified could be "symptomatic of serious problems." "The specific violations noted in this letter and in the Inspectional Observation, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance."

214. After the July 8, 2013 press release announcing preliminary financial results for the

second quarter, analysts did not expect any surprises in Intuitive's earnings conference call on July 18 after the market close. "Due to preannouncement, there should be no surprises in 2Q13 results," said Janney Capital Market's report of July 18. Yet, there was. Guthart disclosed that Intuitive had received an FDA Warning Letter.

215. JP Morgan's July 19, 2013 report characterized the confluence of events resulting in the FDA Warning Letter as a "Perfect Storm." Likewise, an analyst report by Trefis that day said, the "company was dealt another blow in the form of a FDA warning letter, which could hinder approval of new products/procedures going forward." "The warning letter from the FDA will only worsen conditions as it will make it harder for the company to sell the system," it continued.

216. A subsequent *Bloomberg* headline that day also focused on Intuitive's lack of candor with the FDA: "Intuitive Reeling as FDA Cites Lack of Visibility on Problems." It then summed up the situation, stating: "Intuitive … has lost about $6 billion in value over five months after **disclosures about adverse events** with its products, a recent recall, and now, a **regulatory warning it hasn't adequately reported on issues concerning the devices**." In addition, a "**review of Food and Drug Administration records now shows the reports of injuries involving robot procedures have doubled in the first six months of 2013, compared with a year earlier**."

217. Intuitive's stock price declined by $28.81 per share on July 19 to close at $392.67 per share. Intuitive's stock price had not dropped below $400 per share since October 2011. *Bloomberg*'s headline on July 20, 2013 said it all: "Intuitive Surgical Declines On Warning Letter From FDA." The article focused on Intuitive's FDA reporting violations: "FDA inspections in April and May found a number of deficiencies, **including that the [Sunnyvale, California based] company in some cases hadn't adequately reported device corrections and patient adverse events**."

218. It has been alleged that a review of the MAUDE database actually reveals that it is

far worse than *Bloomberg* reported. It has been alleged that for the prior 12 years, from 2000-2012, there were 5,333 da Vinci- related MDRs filed. It has been alleged that this number has dramatically grown to over 8,450 MDRs, after a staggering 3,117 da Vinci related MDRs were filed with the FDA in the nine months from January 1, 2013 to September 30, 2013 alone. With an average rate of over 400 MDRs a month filed during the first seven months of 2013, this is more than five times higher than any prior period since da Vinci was introduced. Until recently, this staggering increase in reported da Vinci-related defects, patient injuries, and deaths in 2013 alone—in comparison to the prior 12 years—was hidden by Intuitive through its dramatic underreporting of MDRs.

219. As a result of defendants' breaches, the price of the Company's stock still has not recovered.

220. Accordingly, as a result of defendants' breaches, the Company has been damaged.

221. Throughout the Relevant Period, Defendants made materially false and misleading statements and omissions about the safety of da Vinci and Intuitive's compliance with FDA regulations. These statements and omissions were false and misleading because they failed to disclose (i) Intuitive's regulatory violations, including the failure to report MDRs, adverse reports, design defects, recalls, and to follow design protocols, (ii) da Vinci's defects and performance problems resulting in injury and death, and (iii) the material rise in da Vinci adverse events. These false and misleading statements and omissions thereby concealed the severity and likelihood of the risks to health posed by da Vinci.

INSIDER TRADING

222. Between February 2012 and March 2013, while in possession of material, adverse, non-public information, the Insider Selling Defendants sold over 380,000 shares of their personally held Intuitive stock, reaping proceeds of over $207 million. Many of these insider sales occurred

immediately after the Company's undisclosed discussions with the FDA in September 2012 regarding reporting requirements, as detailed above. Many other sales took place in late January 2013, just before the first Corrective Disclosures, while Intuitive stock was trading near Relative Period highs, and shortly before substantial declines in the price of the stock. While the timing of certain (but in no way all) of these sales may have been set up in advance (as indicated by "Automatic Sale" in the chart below), it is not clear that the amounts were.

223. The sales of Intuitive stock by defendants Guthart, Mohr, and Smith were highly unusual and suspicious as measured by (i) the total amount and percentage of shares sold, (ii) the contrast with the Inside Trading Defendants' own prior trading history, and (iii) the timing of the sales.

224. The amount and percentage of shares sold during the Relevant Period by defendants Mohr, Guthart, and Smith were extraordinarily large. Defendant Smith's sales totaled $100,068,631, which represented approximately 40% of the total shares he had available for sale during the Relevant Period. Defendant Mohr sold 27,400 shares. Mohr practically sold every share that he acquired during the Relative Period for proceeds of $15,274,248. Defendant Guthart's sales during the Relevant Period totaled $8,743,264, representing approximately 30% of the total shares he had available for sale during the Relevant Period.

225. The illicit insider sales by the Insider Selling Defendants is detailed in the following chart:

	Defendant	Shares		Proceeds ($)
Mar 4, 2013	SMITH LONNIE M	25,000	Automatic Sale at $541.43 per share.	13,535,750
Mar 1, 2013	BROGNA SALVATORE	3,344	Automatic Sale at $553 per share.	1,849,232
Jan 28, 2013	MCNAMARA JEROME J	8,464	Automatic Sale at $574.03 per share.	4,858,589

Jan 28, 2013	MOHR MARSHALL	8,000	Automatic Sale at $574.12 - $574.57 per share.	4,595,000
Jan 25, 2013	HALVORSON ERIC H	1,500	Sale at $577.81 per share.	866,715
Jan 25, 2013	GUTHART GARY S	4,500	Automatic Sale at $577.57 - $578.07 per share.	2,600,000
Jan 25, 2013	MELTZER MARK J	10,000	Automatic Sale at $577.60 - $577.93 per share.	5,778,000
Dec 3, 2012	SMITH LONNIE M	1,000	Sale at $525.98 per share.	525,980
Dec 3, 2012	BROGNA SALVATORE	5,437	Automatic Sale at $528.75 per share.	2,874,813
Nov 27, 2012	SMITH LONNIE M	26,453	Sale at $528.15 per share.	13,971,151
Nov 26, 2012	SMITH LONNIE M	21,164	Sale at $534.34 per share.	11,308,771
Nov 23, 2012	SMITH LONNIE M	20,899	Sale at $536.87 per share.	11,220,046
Nov 21, 2012	SMITH LONNIE M	16,457	Sale at $534.63 per share.	8,798,405
Nov 20, 2012	SMITH LONNIE M	23,949	Sale at $536.67 per share.	12,852,709
Nov 19, 2012	HALVORSON ERIC H	500	Sale at $540 per share.	270,000
Oct 26, 2012	ROSA DAVID J.	6,000	Sale at $538.70 per share.	3,232,200
Oct 22, 2012	MCNAMARA JEROME J	6,250	Automatic Sale at $543.54 per share.	3,397,124
Oct 22, 2012	MELTZER MARK J	10,000	Automatic Sale at $543.59 - $550 per share.	5,468,000
Oct 22, 2012	GUTHART GARY S	4,500	Automatic Sale at $542.98 - $545.63 per share.	2,449,000
Oct 22, 2012	SMITH LONNIE M	17,500	Automatic Sale at $543.29 per share.	9,507,575
Oct 22, 2012	MOHR MARSHALL	7,300	Automatic Sale at $543.02 - $543.22 per share.	3,965,000
Sep 4, 2012	BROGNA SALVATORE	1,250	Automatic Sale at $490.25 per share.	612,812
Aug 13, 2012	MELTZER MARK J	2,000	Automatic Sale at $510.02 per share.	1,020,040
Jul 26, 2012	GUTHART GARY S	1,500	Automatic Sale at $490 per share.	735,000
Jul 25, 2012	MOHR MARSHALL	3,300	Automatic Sale at $478.58 per share.	1,579,314

Jul 24, 2012	GUTHART GARY S	2,000	Automatic Sale at $473.47 per share.	946,940
Jul 24, 2012	SMITH LONNIE M	17,500	Automatic Sale at $473.18 per share.	8,280,650
Jul 24, 2012	MELTZER MARK J	2,000	Automatic Sale at $474.05 per share.	948,100
Jun 1, 2012	BROGNA SALVATORE	2,250	Automatic Sale at $511.78 per share.	1,151,505
Jun 1, 2012	BROGNA SALVATORE	1,094	Sale at $511.78 per share.	559,887
Apr 30, 2012	MOHR MARSHALL	8,200	Automatic Sale at $583.05 - $583.2 per share.	4,782,000
Apr 20, 2012	CASTELLO AUGUSTO V.	26,250	Automatic Sale at $575.13 - $575.34 per share.	15,100,000
Apr 20, 2012	GUTHART GARY S	3,500	Automatic Sale at $574.98 - $575.04 per share.	2,013,000
Apr 20, 2012	MCNAMARA JEROME J	39,144	Automatic Sale at $575.03 - $575.11 per share.	22,511,000
Apr 20, 2012	LEVY ALAN J	4,250	Automatic Sale at $575.08 per share.	2,444,090
Apr 20, 2012	SMITH LONNIE M	17,500	Automatic Sale at $575.09 per share.	10,064,075
Apr 20, 2012	MELTZER MARK J	3,500	Automatic Sale at $575.21 - $575.3 per share.	2,013,000
Apr 20, 2012	HALVORSON ERIC H	2,500	Automatic Sale at $575.08 per share.	1,437,700
Mar 1, 2012	BROGNA SALVATORE	4,594	Automatic Sale at $510.12 per share.	2,343,491
Feb 7, 2012	MORALES COLIN	4,760	Sale at $492.55 - $492.99 per share.	2,346,000
Feb 3, 2012	ROSA DAVID J.	5,000	Sale at $493.59 per share.	2,467,950
Totals:		***380,309***		***$207,280,614***

DERIVATIVE AND DEMAND ALLEGATIONS

226. Plaintiff brings this action derivatively in the right and for the benefit of Intuitive to redress the breaches of fiduciary duty and other violations of law by Defendants.

227. Plaintiff will adequately and fairly represent the interests of Intuitive and its

shareholders in enforcing and prosecuting its rights.

228. The Board currently consists of the following nine (9) directors: defendants Guthart, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk. Plaintiff has not made any demand on the present Board to institute this action because such a demand would be a futile, wasteful and useless act, for the following reasons:

a. Defendants Smith, Guthart, Halvorson and Levy each illicitly sold shares of Intuitive stock while in possession of material, non-public adverse information, during a time in which Intuitive stock was artificially inflated due to Defendants' false and misleading statements. As such, defendants Smith, Guthart, Halvorson and Levy violated the Company's insider trading policy, as set forth in the Code. As a result of these illicit sales, defendants Smith, Guthart, Halvorson and Levy each received direct financial benefits not shared with Intuitive shareholders, and are therefore each directly interested in a demand. Further, defendants Smith, Guthart, Halvorson and Levy each are interested in a demand because they face a substantial likelihood of liability for their breaches of fiduciary duties of loyalty and good faith. Accordingly, demand upon a majority of the members of the Board is excused, and demand is therefore futile;

b. During the Relevant Period, defendants Halvorson, Rubash, and Stalk served as members of the Audit Committee. Pursuant to the Company's Audit Committee Charter, the members of the Audit Committee were and are responsible for, *inter alia*, reviewing the Company's annual and quarterly financial reports and reviewing the integrity of the Company's internal controls. Defendants Halvorson, Rubash, and Stalk breached their fiduciary duties of due care, loyalty, and good faith, because the Audit Committee, *inter alia*, allowed or permitted the Company to disseminate false and misleading statements in the Company's SEC filings and other disclosures and caused the above-discussed internal control failures. Therefore, defendants Halvorson, Rubash, and Stalk each face a substantial likelihood of liability for their breach of fiduciary duties and any demand upon them is futile;

c. The principal professional occupation of defendant Guthart is his employment with Intuitive as its CEO, pursuant to which he has received and continues to receive substantial monetary compensation and other benefits. In addition, according to the Company's Proxy Statement filed with the SEC on March 6, 2013 (the "2013 Proxy"), Defendants have admitted that defendant Guthart is not independent. Thus, defendant Guthart lacks independence from demonstrably interested directors, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action. In addition, defendant Guthart faces a substantial

likelihood of liability for his illicit sales of Intuitive stock, as set forth above;

d. The principal professional occupation of defendant Smith from 1997 until at least 2013 was his employment with Intuitive as its CEO and later as an executive, pursuant to which he received substantial monetary compensation and other benefits. In addition, according to the 2013 Proxy, Smith is not listed as a non-employee director, and Defendants accordingly admit \that defendant Smith is not independent. Thus, defendant Smith lacks independence from demonstrably interested directors, rendering him incapable of impartially considering a demand to commence and vigorously prosecute this action. In addition, defendant Smith faces a substantial likelihood of liability for his illicit sales of Intuitive stock, as set forth above;

e. Defendants Guthart, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk (i.e. the entire Board) signed the false and misleading 2011 Form 10-K. The 2011 Form 10-K was false and misleading because, among other things, it failed to disclose that da Vinci posed a present material health risk to patients, that da Vinci already had known defects, that Defendants had caused Intuitive to violate FDA regulations by failing to report to the FDA corrective actions taken by Intuitive to reduce health risks posed by da Vinci, and that Defendants had caused Intuitive to undertake three secret field actions in October 2011 to reduce risks to health posed by da Vinci that constituted Class II Recalls, as determined by the FDA Warning Letter. Thus, defendants Guthart, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk each face a substantial likelihood of liability, rendering any demand upon them futile; and

f. Defendants Guthart, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk (i.e. the entire Board) signed the false and misleading 2012 Form 10-K. The 2012 Form 10-K was false and misleading because, among other things, it failed to disclose that as of February 4, 2013, at least eight product liability lawsuits alleged that patients had been harmed by Microcracks/insufficient insulation - Monopolar current, and that it was highly likely that additional suits would be filed in the future because da Vinci posed a material health risk to patients, and that while Intuitive had taken corrective actions to reduce health risks in October 2011, hundreds of thousands of surgeries had been performed with da Vinci already before that. The 2012 Form 10-K also failed to disclose that Intuitive was in violation of CGMP, in part, due to critical missing design inputs necessary to address the intraoperative cleaning of Monopolar Scissors, that there had been a substantial number of MDRs and complaints reporting material health risks to patients, and that defendants had caused Intuitive to fail to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50). Thus, defendants Guthart, Smith, Barratt, Halvorson, Johnson, Levy, Loop, Rubash, and Stalk each face a substantial likelihood of liability, rendering any demand upon them futile.

COUNT I

AGAINST ALL DEFENDANTS FOR BREACH OF FIDUCIARY DUTY FOR DISSEMINATING FALSE AND MISLEADING INFORMATION

229. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

230. As alleged in detail herein, each of the Defendants (and particularly the Audit Committee Defendants) had a duty to ensure that Intuitive disseminated accurate, truthful and complete information to its shareholders.

231. Defendants violated their fiduciary duties of care, loyalty, and good faith by causing or allowing the Company to disseminate to Intuitive shareholders materially misleading and inaccurate information through, inter alia, SEC filings, press releases, conference calls, and other public statements and disclosures as detailed herein. These actions could not have been a good faith exercise of prudent business judgment.

232. As a direct and proximate result of Defendants' foregoing breaches of fiduciary duties, the Company has suffered significant damages, as alleged herein.

COUNT II

AGAINST ALL DEFENDANTS FOR BREACH OF FIDUCIARY DUTIES FOR FAILING TO MAINTAIN INTERNAL CONTROLS

233. Plaintiff incorporates by reference all preceding and subsequent paragraphs as if fully set forth herein.

234. As alleged herein, each of the Defendants (and particularly the Audit Committee Defendants) had a fiduciary duty to, among other things, exercise good faith to ensure that the Company's financial statements were prepared in accordance with GAAP, and, when put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

235. Defendants willfully ignored the obvious and pervasive problems with Intuitive's internal controls and practices and procedures and failed to make a good faith effort to correct these problems or prevent their recurrence.

236. As a direct and proximate result of the Defendants' foregoing breaches of fiduciary duties, the Company has sustained damages.

COUNT III

AGAINST ALL DEFENDANTS FOR UNJUST ENRICHMENT

237. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

238. By their wrongful acts and omissions, Defendants were unjustly enriched at the expense of and to the detriment of Intuitive.

239. Plaintiff, as a shareholder and representative of Intuitive, seeks restitution from Defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits, and other compensation obtained by Defendants, and each of them, as a result of their wrongful conduct and fiduciary breaches.

COUNT IV

AGAINST ALL DEFENDANTS FOR ABUSE OF CONTROL

240. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

241. Defendants' misconduct alleged herein constituted an abuse of their ability to control and influence Intuitive, for which they are legally responsible. In particular, Defendants abused their positions of authority by causing or allowing Intuitive to misrepresent material facts regarding its financial position and business prospects.

242. As a direct and proximate result of Defendants' abuse of control, Intuitive has

sustained significant damages.

243. As a result of the misconduct alleged herein, Defendants are liable to the Company.

244. Plaintiff, on behalf of Intuitive, has no adequate remedy at law.

COUNT V

AGAINST ALL DEFENDANTS FOR GROSS MISMANAGEMENT

245. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

246. Defendants had a duty to Intuitive and its shareholders to prudently supervise, manage and control the operations, business and internal financial accounting and disclosure controls of Intuitive.

247. Defendants, by their actions and by engaging in the wrongdoing described herein, abandoned and abdicated their responsibilities and duties with regard to prudently managing the businesses of Intuitive in a manner consistent with the duties imposed upon them by law. By committing the misconduct alleged herein, Defendants breached their duties of due care, diligence and candor in the management and administration of Intuitive's affairs and in the use and preservation of Intuitive's assets.

248. During the course of the discharge of their duties, Defendants knew or recklessly disregarded the unreasonable risks and losses associated with their misconduct, yet Defendants caused Intuitive to engage in the scheme complained of herein which they knew had an unreasonable risk of damage to Intuitive, thus breaching their duties to the Company. As a result, Defendants grossly mismanaged Intuitive.

COUNT VI

AGAINST THE INSIDER SELLING DEFENDANTS FOR BREACH OF FIDUCIARY DUTIES FOR INSIDER SELLING AND MISAPPROPRIATION OF INFORMATION

249. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

250. At the time of the stock sales set forth herein, the Insider Selling Defendants were in possession of material, adverse, non-public information described above, and sold Intuitive common stock on the basis of such information.

251. The information described above was proprietary non-public information concerning the Company's financial condition and future business prospects. It was a proprietary asset belonging to the Company, which the Insider Selling Defendants used for their own benefit when they sold Intuitive common stock.

252. At the time of their stock sales, the Insider Selling Defendants knew about the pervasive issues plaguing the da Vinci system. The Insider Selling Defendants' sales of Intuitive common stock while in possession and control of this material adverse, non-public information was a breach of their fiduciary duties of loyalty and good faith.

253. Since the use of the Company's proprietary information for their own gain constitutes a breach of the Insider Selling Defendants' fiduciary duties, the Company is entitled to the imposition of a constructive trust on any profits the Insider Selling Defendants obtained thereby.

254. Plaintiff, on behalf of Intuitive, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Against all Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of Defendants' breaches of fiduciary duties;

B. Directing Intuitive to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;

C. Awarding to Intuitive restitution from Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by the Defendants;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: February 3, 2014

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Counsel for Plaintiff

VERIFICATION

I, Robert Berg, under penalty of perjury, state as follows:

I am the Plaintiff in the above-captioned action. I have read the foregoing Complaint and authorized its filing. Based upon the investigation of my counsel, the allegations in the Complaint are true to the best of my knowledge, information and belief.

DATED: January 15, 2014

Robert Berg

Robert Berg